Does gaining control of smoking behaviours have a positive impact on glycaemic control in patients with Type 2 diabetes?

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TABLE OF CONTENTS **PAGE**

Glossary of Abbreviations

ANOVA	Analysis of variance
ASH	Action on Smoking and Health (Scotland)
BPS	British Psychological Society
CO	Carbon Monoxide
DSCEP	Diabetes and Smoking Cessation Education Programme
DUK	Diabetes UK
HbA1c	Glycated haemoglobin
HBM	Health Belief Model
IDDM	Insulin dependent diabetes mellitus
IFCC	International Federation of Clinical Chemistry
LREC	Lothian Research Ethics Committee
MDS	Minimum data set
MI	Motivational Interviewing
Mmol/mol	millimoles per microlitre
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NIDDM	Non-insulin dependent diabetes mellitus
PATH	Partnership Action on Tobacco and Health
PCDS	Perceived Control of Diabetes Scale
RCT	Randomized controlled trial
RNIBP	Royal National Institute for Blind People
SDF	Scottish Diabetes Framework
SIGN	Scottish Intercollegiate Guidance Network
SLoCS	Smoking Locus of Control Scale
T1	Baseline measure
T2	12-month follow-up measure
TBP	Theory of Planned Behaviour
USA	United States of America
WHO	World Health Organisation

Table 1: Biomedical Measures and Recommended Levels

Measure	Name	Recommended Level
BG Type 2	Blood Glucose Type 2	4-7 mmol/L (pre-prandial) Under 8.5 mmol/L (post-prandial) (Diabetes.co.uk [accessed April 2015])
HbA1c	Glycated Haemoglobin	48mmol/mol (6.5%) (no recommendation given for pre- and post-prandial) Diabetes.co.uk [accessed April 2015)
CO	Carbon Monoxide	0-8ppm (non-smoker) or 0-9.16mg/m3 (WHO, 2011)

Abstract:

Background

Smoking cigarettes is a well-documented cause of ill-health and is associated (Cigarette smoking among people with diabetes increases the risk of developing long-term complications. Although smoking cessation is considered important for all, it is especially significant for people with diabetes and is recommended throughout the literature. Few studies have investigated the impact of a smoking cessation intervention tailored to the needs of people with Type 2 diabetes. This study attempts to address this.

Aims

The overall aim was to assess the impact of a smoking cessation psychological intervention for people with Type 2 diabetes and whether the intervention had a positive impact on their glycated haemoglobin levels.

Methodology

Design: This was a quantitative longitudinal smoking cessation psychological intervention with no control group.

Participants: Participants were 31 adult patients (n=14 males, n=17 females) with Type 2 diabetes who regularly smoked cigarettes.

Primary Outcome Measures: Using a minimum data set and validated scales, glycated haemoglobin (HbA1c) and carbon monoxide (CO) levels were recorded and the Perceived Control of Diabetes Scale (PCDS) and Smoking Locus of Control Scale (SLoCS) administered to investigate changes in participants perceptions of their diabetes and smoking behavioural control across the subscales.

Secondary Outcome Measures: Readiness to stop smoking (likes, dislikes, motivation and confidence), concerns relating to smoking, awareness of smoking cessation products and services and knowledge of health risks associated with smoking and diabetes were measured for comparison. Participant weight (kg) was also measured as a precaution.

Procedure: Participants were recruited in Falkirk Royal Infirmary at their annual diabetes review. Measures were recorded at baseline immediately prior to the health intervention. This was repeated at 12-month follow-up.

Data Analysis: Data were analysed at T1 and T2 with SPSS 17 using within-factors repeated measures ANOVA.

Results: Positive effects post-intervention were found for: HbA1c ($p<0.0005$) and CO ($p<0.0005$) levels, PCDS ($p<0.0005$) and SLoC ($p<0.0005$) Internality subscales and for dislikes ($p<0.003$), motivation ($p<0.0005$, confidence ($p<0.0005$) and knowledge of associated health risks ($p<0.0005$). No participants stopped smoking during this study.

Conclusion: The results demonstrate a positive impact on health behaviour change showing an increase in the likelihood that participants will take greater control of their glycated haemoglobin levels and smoking behaviours and will be more motivated and confident to do so. With no control group the design does not control for all factors that may have contributed to these changes.

Keywords: Smoking cessation, glycated haemoglobin levels, health behaviour change

Chapter 1 - Introduction

The interest for this research was fostered during Health Psychology Stage 1 training at University of Stirling. A work-based placement in smoking cessation clinics in Forth Valley led to Maudsley Training in smoking cessation techniques with Professor Peter Hajek who is a widely published academic and renowned world leader in smoking cessation. Hajek's techniques were developed during his tenure at the Maudsley Hospital in London (Hajek, 1994). The Stage 1 placement led to two NHS funded posts. The first was an audit of smoking cessation provision across Forth Valley by primary and secondary care and pharmacy and was in collaboration with University of Stirling. The second post was as a smoking cessation specialist advisor.

During a lecture on applications of health psychology within the NHS, the lecturer advised that the prevalence of diabetes was predicted to increase substantially and that it could be a field to consider for research or applied psychology.

This inspired a literature search on PubMed, Cinahl, NES and other relevant sites using MESH terms such as 'Diabetes; Health Promotion; Lifestyle; Behavior Therapy; Counseling; Diabetes Complications; Treatment Outcome. The review and parameters are discussed more fully in Chapter 2. One important finding was a definition of diabetes care and who should be involved. With an increasing prevalence in the development of diabetes

among the population of Scotland The Scottish Health Plan – *Our National Health: A plan for action, a plan for change* (Scottish Executive Health Department, 2000) – acknowledged the need to make a significant impact on diabetes care and committed to producing a Scottish Diabetes Framework (SDF, Scottish Executive Health Department, 2001) to contain the growth of diabetes and guide the changing landscape of diabetes care over the next ten years. The SDF worked alongside the SIGN clinical guideline on the management of diabetes and the clinical standard for diabetes care (Scottish Intercollegiate Guidelines Network 55, 2001). The SDF was published in March 2002 and as the prevalence of diabetes continued to increase by 4% per year, was superseded by the Scottish Diabetes Framework Diabetes Action Plan 2006 (Scottish Executive, 2006) and continued on in the Diabetes Action Plan 2010 Quaity Care for Diabetes in Scotland (Scottish Executive, 2010), aligned with SIGN 116 (SIGN 116, 2011). The SDF set out seven first stage priorities: Patient Information, Education and Empowerment; Heart Disease; Eye Care; Strategy, Leadership and Team working; Education and Training for Professionals; Information Maintenance & Technology and Diabetes Registers; Implementation and Monitoring. The Diabetes Action Plan 2010 built on these by adding: Improve quality of care and outcomes; Enhance Diabetes Managed Clinical Networks; Increase diabetes research; Support initiatives to promote healthier lifestyles; Improve dissemination of diabetes information. Diabetes Care in Forth Valley is structured and informed by the SDF and subsequent action plans.

Another important finding that permeated throughout the literature review was a recommendation that people with diabetes be given specialist smoking cessation support tailored to their needs. This prompted a systematic literature review (SLR), discussed more fully in Chapter 2, on smoking cessation interventions designed for this population which produced very little material. A full copy of the review is included at the end of the thesis (pg. 221) (The SLR was submitted to the British Journal of Health Psychology in 2010 for peer review and was rejected for publication on the grounds of being too specific and not generalizable to the wider public). Diabetes Care in Falkirk Royal Infirmary was approached with a request to run a research project aimed at delivering a specialist smoking cessation intervention to patients.

Permission was granted with an invitation to shadow the diabetes consultants to introduce diabetes care and departmental processes and procedures. During shadowing it became evident that many patients found it challenging to maintain their glycated haemoglobin levels (HbA1c) within the recommended levels of 6.5% (NICE, 2009) and diabetes-related complications had developed as a result. HbA1c is an average measurement of the previous 2-3 months of blood glucose per litre of blood. At the time NICE (2009) recommended HbA1c be measured in percentages although the International Federation of Clinical Chemistry (IFCC) felt the measurements were conflicting and confusing for people with diabetes. The major concern was that a 1% increase in HbA1c could appear small to the person yet in clinical terms had serious implications for increased risk of complications (IFCC,

2004). After developing a working group (Sacks, 2005) and trialing the proposed changes with 30 assays from across the world, the IFCC (2008) introduced mmol/mol (6.5% = 48mmol/mol) as the new HbA1c measure for reporting (Nordin & Dybkaer, 2007). NICE acknowledges this in CG87, Management of Type 2 Diabetes (2009) and advises the changes will be included in the update due for release in 2015.

The Diabetes UK (DUK) website (accessed August 2014) refers to both methods of reporting and includes a converter for people familiar with the previous format (DUK, 2014). The utility of this is unclear almost seven years after the new system was introduced. It also refers to mmol/l, referencing NICE 2008, which conflicts with the evidence presented above.

Control was often mentioned in consultations as it is in smoking cessation sessions. Smoking cessation is based on control of health behaviours and cravings and shadowing highlighted a common link between the two. Questions arose as to whether patients struggling to control glycated haemoglobin levels after the direct approach from healthcare, would achieve more satisfactory glycated haemoglobin levels by an indirect approach? Would learning to control smoking behaviours transfer to controlling glycated haemoglobin levels or other risk factors for long-term complications? Was control therefore a transferable skill?

These questions led to the development of an exploratory study measuring the efficacy of a smoking cessation intervention for patients with Type 2 diabetes. To facilitate the study the researcher developed the Diabetes and Smoking Cessation Education Programme (DSCEP). The DSCEP was based on previous involvement in smoking cessation interventions and was guided by the Lead Smoking Cessation Specialist Nurse and Lead Diabetes Specialist Nurse from Falkirk Royal and Infirmary with advice from supervisors at Queen Margaret and Stirling Universities.

The research investigated smoking locus of control and perceived behavioural control of diabetes using the Smoking Locus of Control Scale (SLoCS) (Georgiou & Bradley, 1992) and the Perceived Control of Diabetes Scale (PCDS) (Bradley, 1993). The DSCEP provided education on health risks associated with diabetes and smoking and how these risks could be minimized by stopping smoking. It was delivered using motivational interviewing techniques and was aligned with the Intervention Method during Consultation (Rollnick, Butler & Stott, 1997). It was anticipated the DSECP would encourage a cognitive shift in participants from an external locus of control to an internal locus of control, thus eliciting positive health behaviour change. The preferred outcomes were for patients to stop smoking and for their glycated haemoglobin levels to have reached recommended levels.

Chapter 2 is a critical review of the smoking and diabetes literature. It includes a discussion on the psychology of smoking behaviours and of self-managing diabetes and on the utility of psychology to understanding these behaviours. The chapter concludes with the rationale behind the research.

Chapter 2 - Review of Smoking and Diabetes Literature

Action on Smoking and Health (ASH) Scotland is an independent charity whose aim is to reduce harm caused by tobacco use. ASH Scotland is the leading advisor on tobacco strategies, stop smoking interventions and training and influencing public attitudes to tobacco and smoking. ASH advises, 'In the light of the growing evidence demonstrating that smoking is an independent risk factor for diabetes and that it is also an aggravating factor for diabetes complications, smoking cessation advice should be a routine component of diabetic care' (ASH Scotland, 2002). In order to develop an intervention to address this, it is important to understand patient perceptions about their control of diabetes and smoking behaviours.

2.1 Smoking – an overview

Smoking is recognized as the most important preventable cause of ill-health and premature death in Scotland, directly linked to more than 13,000 deaths every year. It is associated with diseases of the heart and blood vessels, lungs, stomach, kidneys and other organs and it is estimated that NHS Scotland spends over £300 million every year on treating smoking-related diseases (Scottish Public Health Observatory, 2012).

The health statistics of people with diabetes who smoke give cause for concern. The major cause of morbidity and mortality associated with diabetes

is from the risk of atherosclerotic macrovascular disease which increases if the individual smokes cigarettes (Law & Wald, 2003; Doll, Peto, Boreham & Sutherland, 2004; SIGN 97, 2007; SIGN 116, 2011; British Heart Foundation, 2012; DUK, 2012).

Cigarette smoking has been reported as a significant risk factor for death by coronary heart disease in people with Type 2 diabetes in the Finnish Prospective Study (Tuomilehto, Rastentve, Jousilati, Sarti & Vartainien, 1996), the Paris Prospective Study (Fontbonne & Eschwège, 1991) and the Multiple Risk Factor Intervention Trial (MRFIT Research Group, 1982). Former cigarette smokers with Type 2 diabetes are 1.54 times more likely to be diagnosed with coronary artery disease (Miegs, Singer, Sullivan, Dukes, D'Agostino, *et al*., 1997). Similar results were reported adding to the evidence base that smoking increases the risk of morbidity and mortality from macrovascular complications (Dean, Mathews, Dolben, Carolan, Luzio & Owens, 1994; Hanefield, Fisher, Julius, Schulz and Ziegelasch, *et al.,* 1996).

Several studies have documented the relationship between smoking and the development of nephropathy in Type 2 diabetes (Chuahirun, Khanna, Kimball & Wasson, 2003; Chuahurin, Simoni & Hudson *et al*., 2004). Smoking is also documented as a risk factor for both the development and progression of various types of neuropathy (Tesfaye, Chaturvedi, Eaton, Ward, Manes *et al*., 2005; Booya, Bandarin, Larijani, Pajouhi, Nooraei & Lofti, 2005).

While previous studies have suggested a positive relationship between cigarette smoking and retinopathy (Reichard, 1992; Morgando, Chen, Patel, Herbert & Kohner, 1994), subsequent research has not found evidence to support this relationship (Eliasson, 2003; Sinclair, Delvecchio, Malamut & Li, 2005). On their website The Royal National Institute for Blind People (RNIBP) do not correlate Type 2 diabetes and retinopathy with smoking. Their position is that good diabetes control, which includes maintaining weight and stopping smoking, significantly reduces the risk of developing retinopathy. It is not clear if this statement denotes statistical significance and to what value or percentage. RNIBP also state that nerve damage, cardiovascular and kidney disease are more common in smokers with diabetes. This can lead to hardening of the arteries which raises blood pressure and glycated haemoglobin levels making diabetes harder to control (RNIBP, 2014).

Although smoking is a well-established risk factor for cardiovascular and other diseases, Ahmed and Memon, (2008) argued that there is conflicting evidence regarding the effect of smoking on glycated haemoglobin control (Ahmed & Memon, 2008). They investigated smoking and its relationship with blood pressure and blood glucose in patients with coronary heart disease in Karachi. Thirty participants were assigned to the control group and had no evidence of coronary heart disease. A further 120 participants with coronary heart disease were sub-divided into Stable Angina, Unstable Angina, Acute Myocardial Infarction and Old Myocardial Infarction groups. The study reports no significant statistical difference between the smokers and the control group in

terms of haemoglobin, haematocrit and serum blood glucose and concludes that smoking history is not related to diabetes.

This is not supported by a study of 103 Iranian women in Tehran, 10% of whom smoked cigarettes (Ghazanfari, Niknami, Ghofranipour, Larijani, Agha-Alinejad & Montazeri, 2010) or by the RNIBP (2014), DUK (2014) or ASH Scotland (2014) who all associate smoking with the deleterious effects of diabetes.

The risks of not self-managing diabetes effectively are clear. So too are the consequences of smoking, whether living with diabetes or not, and the increased risks if diabetes is present (DUK, 2014; ASH Scotland, 2014). To design an intervention to encourage positive health behaviour change, it is critical to understand the psychology underpinning cigarette smoking.

The following section discusses the psychology of cigarette smoking in an attempt to understand why people initiate and maintain the behaviour in light of the breadth of information on its potentially destructive properties.

2.2 Psychology of Smoking

Smoking is a complex behaviour involving biological, psychological and social processes. Recruitment to smoking is more prevalent among adolescents. This is not a coincidence as tobacco companies are heavily reliant on young people becoming addicted to smoking cigarettes to increase their market shares. In a systematic review of 19 longitudinal studies conducted across the USA, Australia, Spain Germany and England it was suggested that to succeed, tobacco marketing must appeal to young people's sensibilities and target key concerns such as identity, social, peer and parental approval and adventure seeking thus fulfilling psychological and social needs (Lovato, Watts & Stead, 2012).

In a review of 7 randomised controlled trials (RCTs) conducted across the USA, Germany, the Netherlands, Canada and Finland it was found that adolescent smoking usually continues into adult smoking with the majority already addicted to the behaviour by 18 years of age. Uptake of smoking at this early stage provides more life-years for tobacco use, is associated with heavier tobacco use and increased likelihood of tobacco-related morbidity and mortality (Johnston, Liberato & Thomas, 2012). By focusing on RCTs the reviewers have limited the information to synthesize and could have included the findings from reviews as a further stream to report. They have also eliminated studies because the investigators did not provide an incentive as part of the intervention, which again could have been another information stream to include in the Cochrane review (2012).

One of the ingredients of cigarettes is nicotine. It is used industrially as an insecticide and has highly addictive properties when ingested (Attar-Zadeh, 2013). When taken in small quantities nicotine delivers a range of psycho-physiological effects including tranquilization, weight loss, increased alertness and cognitive function (Rose, 1996). The nicotine paradox (Nesbitt, 1973) attempts to explain the conflict between relaxation and stimulation and concludes that smoking delivers nicotine which relieves withdrawal symptoms thus returning the smoker to a state of contentment (Hughes, 1991; Foulds & Ghodse, 1995).

Over time, a physical dependence occurs. Several tobacco companies have openly admitted that smoking is highly addictive. In 1997 the Ligget Group, formerly known as the Ligget & Myers Tobacco Company based in Durham, North Caroline, USA, admitted it had increased the nicotine content in cigarettes to boost their addictive properties (Porter, 1997). The nicotine regulation model of smoking describes a regulatory mechanism that monitors nicotine levels in the brain. When levels fall below what the individual feels is comfortable, they smoke to top-up their nicotine levels thus alleviating feelings of withdrawal (Schachter, Silverstein, Kozlowski, Herman & Leibling, 1984).

In 1995, Hajek and colleagues challenged this theory and highlighted that some smokers will smoke nicotine-free cigarettes and abstain for lengthy periods, when for example, on a long-haul flight or hospital stay. They further

argued that light smokers typically smoke five or less cigarettes per day which would be insufficient to maintain a high level of nicotine, (Hajek, West & Wilson, 1995). It was later suggested that these findings could be attributed to the psychosocial environment and its ability to protect very light smokers from nicotine dependence and higher tobacco consumption (Lindström & Östergren, 2001).

A more recent study in Finland among adult twins (Korhonen, Broms, Levalahti, Koskenvuo & Kaprio, 2009) supports these views and highlights that few studies exist that have explored the characteristics of light/intermittent smokers. They note that in the USA while regular smoking rates decreased from 24% (1999) of the population to 21% (2006) intermittent smoking rates increased from 18% to 20% respectively. The same was not found in Finland across the same time frame with intermittent rates remaining constant at 6%. Worryingly the authors note that evidence on health consequences of intermittent smoking is limited and suggest this may be attributed to intermittent smokers being excluded from studies due to the dose-response relationship of the health effects of smoking for many diseases. They conclude their study suggesting that intermittent smokers are less dependent on tobacco and use less tobacco products, have healthier lifestyles, have higher levels of education and possess better mental health profiles (Korhonen, Broms, Levalahti, Koskenvuo & Kaprio, 2009).

The notion that smokers are more likely to have additional behavioural and cognitive issues such as anxiety is much debated. The Nicotine Addiction Model (Schachter, 1978) focuses on explaining the maintenance of the smoking behaviour after acquisition. In one study in the USA the intensity of electric shock the participant was able to tolerate was used as a behavioural measure of anxiety (Steffy, Michenbaum & Best 1970). The results demonstrated that heavy smokers tolerated a higher intensity of shock and were therefore considered less anxious when allowed to smoke than when not allowed to smoke. It can be argued that rather than non-smokers exhibiting less anxiety, smokers are constantly exposed to withdrawal symptoms, increasing their feelings of anxiety. The study failed to account for the sedative properties of smoking and of the psychological and social influences on tobacco use (Pomerlau, 1979; Royal College of Physicians, 2000; van Gucht, Van den Bergh, Beckers & Vansteenwegen, 2010).

Eysenck, Tarrant and Woolf (1960), found smokers rated highly on measures of extraversion. This personality trait has been associated with sensation seeking behaviours and found to be more prevalent in young adult populations (Bradley & Wildman, 2002), findings supported by Lovato, Watts and Stead, (2012). Sensation seeking is described as a quest for novel and intense experiences that may pose a risk to the sensation seeker. It is suggested that sensation seekers have lower levels of tonic arousal and seek intense stimulation to increase levels of cortical arousal. This suggestion supports findings from a study that found higher sensation seeking scores in a

group of smokers compared to a group of non-smokers (Carton, Houezec, Lagroue & Jouvent, 2000).

These findings are not supported in a study of 130 male psychology undergraduate students at Nebraska University, USA. The report suggests neuroticism is the key personality characteristic that determines smoking uptake in young neurotic males and suggests smoking may be used as a buffer to alleviating symptoms of depression (McChargue, Cohen & Wrath Cook, 2004), consistent with the view that neuroticism is a precursor to depression (Jorm, Christensen, Henderson, Jacomb, Korten & Rodgers, 2000).

Bonas (2005) suggests that people smoke as a result of behaviour learned from others in a position of influence, for example, friends and family and media icons and that smokers learn to respond to conditioned stimuli and use smoking as an escape or avoidance mechanism in response to particular aversive states (Bonas, 2005).

Although the literature draws differing conclusions on the uptake of smoking in adolescents and continuation of the behaviour into adulthood, it universally establishes that smoking has biological, psychological and social factors (Johnston, Liberato & Thomas, 2012).

The present study explores the efficacy of a smoking cessation intervention for people with diabetes. In order to develop an effective intervention it is important to have an understanding of the disease and of its implications for long-term health. The following section is a critical discussion of diabetes and the psychology of self-management.

2.3 Diabetes – an overview

Diabetes is a chronic, long term condition that is concerned with the production and uptake of the hormone insulin. Insulin is produced in the pancreas and enables cells to absorb glucose which is turned into energy. In diabetes the pancreas does not produce enough insulin or the body is unable to use the insulin effectively and cannot regulate blood glucose levels. This causes glucose to accumulate in the blood, which can lead to long-term complications (Tierney, McPhee & Papadakis, 2002; Rother, 2007).

Acute complications including hypoglycaemia (low blood glucose levels), diabetic ketoacidosis (the chemical balance of the body becomes too acidic) or hyperosmolar hyperglycaemic state (related to diabetic ketoacidosis where high blood glucose levels can lead to dehydration resulting in a high risk of complications, coma and death) occur if the disease is not adequately controlled. Serious long-term complications include cardiovascular disease, chronic renal failure and stroke (Donnan, Fisher, Macleod & Davis, 2008), and

various types of nerve damage, which can cause erectile dysfunction and poor wound healing (Mailloux, 2007).

Because diabetes affects blood circulation, feet and fingertips are particularly susceptible to the effects of the condition. Poor wound healing can lead to gangrene, and in some cases, to amputation. Appropriate treatment of diabetes, including education on the effects of blood pressure control and lifestyle factors such as smoking (Aveyard & West, 2007) and body weight (Barnard, Cohen, Jenkins, Turner-McGrievy, Gloede, Jaster, *et al.,* 2006), may help to reduce the risk of developing most of the chronic complications. Diabetes is the most significant cause of adult blindness in the non-elderly and the leading cause of non-traumatic amputation in adults, in the developed world. In the United States of America diabetic nephropathy is the most common condition associated with renal dialysis (Mailloux, 2007).

There are many types of diabetes recognised by the medical profession. The two most commonly known are Type 1 and Type 2 diabetes (DUK, 2012; SIGN 2011; Tierney, McPhee & Papadakis, 2002).

2.3.1 Type 1 Diabetes

The term "Type 1 diabetes" has universally replaced several former terms, including childhood-onset diabetes, juvenile diabetes, and insulin-dependent

diabetes mellitus (IDDM). Although Type 1 can affect children or adults it represents the majority of cases in children (DUK, 2014; Rother, 2007). It is characterized by the loss of the insulin-producing beta cells of the islets of Langerhans in the pancreas leading to a deficiency of insulin and can be further classified as immune-mediated or idiopathic. The majority of Type 1 is of the former where beta cell loss is a T-cell mediated autoimmune attack. To date there is no known preventive measure against Type 1 (DUK, 2014).

The principal treatment of Type 1, even in its earliest stages, is the delivery of artificial insulin via injection combined with careful monitoring of blood glucose levels using blood testing monitors. The average glucose level for people with Type 1 should be as close to normal, 48mmol/mol, as is safely possible. Values above 75mmol/mol are often uncomfortable resulting in frequent urination. Although not immediately life-threatening this can lead to ketoacidosis which could lead to coma or death and will require medical attention (Kitabchi, Umpierrez, Murphy & Kreisberg, 2006). Treatment must be continued indefinitely in essentially all cases and although insulin replacement can be burdensome, need not significantly impair normal activities if sufficient patient training, awareness, appropriate care, discipline in testing and dosing of insulin is taken (DUK, 2014).

In contrast, some GPs suggest 53-58mmol/mol for those experiencing frequent low blood glucose levels or hypoglycaemia as this can lead to

seizures or episodes of unconsciousness and must be treated immediately. The person or child must stop what they are doing immediately and eat or drink something sugary. Although it is not clear from the literature how to treat very young children who perhaps cannot articulate feeling unwell, DUK recommend a finger prick test in all cases (DUK, 2014).

Treatment emphasis is now also placed on lifestyle adjustments such as diet and exercise though these cannot reverse the progress of the disease. Apart from the common subcutaneous injections (Marks & Miller, 2006), it is also possible to deliver insulin by a pump, which allows continuous infusion of insulin 24 hours a day at pre-set levels, and the ability to programme doses of insulin as needed at meal times (DUK, 2014; Lenhard, & Reeves, 2001).

2.3.2 Type 2 Diabetes

Similarly to Type 1, the term "type 2 diabetes" has replaced several former terms, including adult-onset diabetes, obesity-related diabetes, and non-insulin-dependent diabetes mellitus (NIDDM). Type 2 tends to be diagnosed in older adults and recently has become more prevalent in younger people across all ethnicities accounting for 85-90% of all cases (DUK, 2014). Type 2 is characterized differently to Type 1 and is due to insulin resistance or reduced insulin sensitivity, combined with relatively reduced insulin secretion which in some cases becomes absolute. The defective responsiveness of body tissues to insulin almost certainly involves the insulin receptor in cell

membranes (DUK, 2014; Ward and Lawrence, 2000). As yet the specific defects have not been identified.

In the early stages of Type 2 the predominant abnormality is reduced insulin sensitivity, characterized by elevated levels of insulin in the blood. At this stage hyperglycaemia can be reversed by a variety of measures such as diet, exercise and lifestyle modifications. Medication that improves insulin sensitivity or reduce glucose production by the liver can also be prescribed as an adjunct. As the disease progresses, the impairment of insulin secretion worsens, and therapeutic replacement of insulin often becomes necessary (DUK, 2014).

In some cases people can spend many years in a state of pre-diabetes, a condition that occurs when a person's glycated haemoglobin levels are higher than normal but not high enough for a diagnosis of type 2 diabetes (Lilly & Godwin, 2009).

2.3.3 Prevalence of Type 2 Diabetes

The prevalence of diabetes worldwide is increasing beyond previous estimates. It is correlated with an ageing population that is becoming increasingly obese as a result of a sedentary lifestyle and reduced physical activity (Boyle, Honeycutt & Narayan, 2001). Type 2 diabetes represents 90%

of all cases and despite efforts to manage risk factors, develop new treatment strategies and administer new therapies, people with Type 2 diabetes in the UK have a threefold increased risk for cardiovascular mortality (3.25 [2.87-3.68] adjusted for smoking) (Taylor, Heneghan, Farmer, Fuller, Adler, Aronson & Stevens, 2013), highlighting challenges for health care. Adopting a healthier lifestyle is central to preventing and managing the disease (NICE PH38, 2012).

The World Health Organisation (WHO) has estimated that the prevalence of Type 2 diabetes will increase to 300 million people worldwide by 2025 (King, Aubert & Herman, 1998). Arguably, these figures are underestimated (Saydah, Loria & Eberhardt, 2001; Taubert, Winkelman & Schlieffer, 2003). The Yorkshire and Humber Public Health Observatory (2010) reported the number of people over 16 years of age in England with diagnosed and undiagnosed diabetes to be 3.1 million accounting for 7.4% of the population. It is not clear in the report how the undiagnosed cases were accounted for. The report estimates these figures will increase to 4.6 million and 10% respectively by 2030 and that 90% will be Type 2 diabetes with many already having prediabetes (Danaei, Finucane, Lu, Singh, Cowan, Paciorek, *et al*., 2011). Diabetes UK (2012) estimate this figure could be as high as 850,000 adults in England.

Because of its silent onset*, many people will already have detectable signs of one or more long-term complications by the time Type 2 diabetes is diagnosed. The life expectancy of a patient is reduced by approximately 8-10 years and they are five times more likely to develop cardiovascular disease and experience stroke resulting in death in nearly 70% of cases compared to those without the disease (DUK, 2012; SIGN 116, 2011).

The cost to the NHS in England of treating Type 2 diabetes and its complications is currently £8.8 billion per year, 8% of its total budget. Indirect costs resulting from loss of productivity and premature death are estimated to be £13 billion (Hex, Bartlett, Wright, Taylor & Vardley, 2012). The NHS has already seen substantial financial increase to treat diabetes. Drug prescribing rose from £514 million to £725 million from 2005/06 to 2010/11 respectively (NHS Information Centre for Health and Social Care, 2011) and this is expected to continue with estimates rising from £15 billion to £20 billion for direct and indirect costs respectively by 2036/37 (Hex *et al*., 2012).

In Scotland Type 2 diabetes is an increasing health problem across all age groups. In response to the document 'Towards a Mentally Flourishing Scotland, (2009)', DUK reported the prevalence of diabetes as 4% but warned this figure was expected to increase to at least 5% by 2010 (McGinley, 2008). These estimates have not yet been achieved although figures are steadily

* To celebrate their 75th Anniversary in 2009, Diabetes UK launched the 'Silent Assassin' campaign.

increasing toward the projected percentage. At the beginning of 2012, the Scottish Diabetes Survey reported approximately 250,000 people registered with diabetes, compared with approximately 240,000 in 2010, 4.7% and 4.6% of the population respectively. Type 2 diabetes was diagnosed in 88% of all cases (DUK, 2012). Type 2 diabetes and the associated long-term complications are costing the NHS in Scotland £1bn per year to manage. This equates to approximately 10% of the total NHS Scotland budget (DUK, 2012; Robison, 2008).

The causes and mechanisms of Type 2 diabetes are the subject of many theories. Fat concentrated around the waist in relation to abdominal organs is known to contribute to insulin resistance. Central obesity is active hormonally, secreting adipokines, a group of hormones known to impair glucose tolerance (MacDougald, Ormond & Burant, 2007; Diabetes UK, 2012).

Other factors include ageing and genetic predisposition (DUK, 2012; Rosenbloom & Silverstein, 2003). Environmental exposures may also contribute to increased prevalence, for example, a positive correlation has been found between the concentration of bisphenol A, a constituent of polycarbonate plastic, in urine and the increased prevalence. The authors suggest this may be associated with avoidable morbidity and warrants further investigation (Lang, Galloway & Scarlett, 2008).

Patient education, understanding and active participation in the management of the condition is vital. People who maintain good glycated haemoglobin control present with less long-term complications of diabetes and the complications are not so severe (DCCTRG, 1995; Nathan, Cleary & Backlund, 2005). Other health problems and lifestyle choices can accelerate the deleterious effects of diabetes, in particular weight gain and obesity. In an attempt to counter this, a collaborative study is currently running between the University of Glasgow and Newcastle University. Results are due in 2018. The study builds on the findings of a preliminary trial at Newcastle University investigating direct routes to Type 2 remission. Under close medical supervision, participants' food intake was reduced to 800 calories per day and comprised liquid diet drinks and non-starchy vegetables. Within one week levels of fat in the liver had reduced significantly. By the end of the study fat levels in the pancreas had also decreased and insulin production had returned to normal. Although some participants gained weight, Type 2 remission was maintained at 2-month follow-up (Lim, Hollingsworth, Aribisala, Chen, Mathers, Taylor, 2011).

Although this study may offer hope in the future diabetes currently has no known cure. It is managed mostly in the community by the individual with support from primary care with the focus on managing or reducing the risk of complications and relies on patient education, dietetic support, sensible exercise and self-monitoring (Perlmutter, 2008).

As Boyle, Honeycutt and Narayan (2001) reported, the role of lifestyle and behavioural factors in patients with Type 2 diabetes, such as smoking, has been shown to contribute to poor self−management and more rapid disease progression. Changing these behaviours can reduce the risk of developing diabetes and delay the onset of long−term complications (Canga, de-Irala, Vara, Duaso, Ferrer & Martinez-Gonzalez, 2000; Glasgow, 2000).

In order to change behaviour it is important to understand the psychology underpinning the behaviour. The following section discusses the psychology of self-managing diabetes and how it can affect glycated haemoglobin levels.

2.4 Psychology of Diabetes

Diabetes is a complex condition that places high behavioural demands on the individual living with the disease. While access to well-trained healthcare professionals is a key aspect of diabetes care the burden of care remains with the individual. Although many people cope well with their condition, the rates of psychological issues, such as depression, anxiety and stress, and poor quality of life are much higher among those with diabetes than in the general population (Ali, Stone, Peters, Davies & Khunti, 2006; Das-Munshi, Stewart, Ishmail, Bebbington, Jenkins & Prince, 2007).

In a study exploring the psychosocial problems and barriers to improved diabetes management (the DAWN Study), Peyrot, Rubin, Lauritzan, Snoek, Matthews & Skovlund, (2005) report that 41% of participants demonstrated low levels of psychological wellbeing as measured against the WHO-5 Wellbeing Index. The study reports that only 12% of the Type 2 population had received psychological support in the preceding five years. The study failed to compare the low levels of psychological wellbeing among its participants to those of the general population.

These findings are important for clinicians and patients as poor psychological well-being can have a negative impact on their ability to self-manage their diabetes. For example, adherence to medication can be reduced resulting in poor outcomes (Gonzalez, Safren, Cagliero, Wexler, Delahanty, Wittenberg, *et al*., 2007; Gonzalez, Safren, Cagliero, Wexler, Miegs & Grant, 2008; Gonzalez, Peyrot, McCarl, Collins, Serpa, Mimiaga, *et al*., 2008; Gonzalez, McCarl, Wexler, Cagliero, Delahanty, Soper, *et al.,* 2010). In addition to the severe impact of psychological problems, undetected depression can result in increased healthcare costs and expenditure (Egede & Zheng, 2003), lost productivity due to absence from work (Egede, 2007) and increased mortality (Katon, Rutter & Simon *et al*., 2005).

Treatment for psychological issues such as anxiety and depression has been shown to reduce symptoms and improve blood glucose control and quality of

life (Lustman & Clouse, 2005; NICE, 2009) as well as improve psychological wellbeing (Ismail, Winkley & Rabe-Hesketh, 2004; Winkley, Ismail, Landau & Eisler, 2006) and reduce healthcare costs (Simon, Katon, Lin, Rutter, Manning, von Korff, *et al*., 2007). In addition, understanding the individual's health beliefs, attitudes toward their condition and levels of confidence and motivation to self-manage diabetes may lead to the development of interventions that could help them control their blood glucose levels and improve their ability to cope with the disease (Ruggiero, 2000; van der Ven, 2003; Collins, Bradley, O'Sullivan & Perry, 2009).

There is continued debate as to the cause of psychological distress in people who self-manage diabetes. To inform this debate, longitudinal studies need to investigate causal factors further and identify whether psychological distress is due to the fear of developing long-term complications, the risk of hypoglycaemia or to diabetes-related abnormalities in neurohormonal and neurotransmitter functioning (Grigsby, Anderson, Freedland, Clouse & Lustman, 2002).

Nonetheless, research on the subjective experiences of people with diabetes have highlighted a relationship between psychological distress and blood glucose control both directly through the hyperglycaemic effects of stress hormones and indirectly through the disruption of self-management techniques (Rubin & Peyrot, 1992).

Riazi, Pickup and Bradley (2004) defined stress as hassle that people deal with in every-day situations. In their study they demonstrate the individual differences in stress-reactivity and suggest that this should be considered when evaluating the research and clinical use of stress-management interventions. No large population data are available to inform this debate.

Research on diabetes-related emotional distress has consistently reported that worrying about developing long-term complications and feeling guilty and anxious when self-management is not effective, are the most distressful (Snoek, Pouwer, Welch & Polonsky, 2000). Meltzer & Egleston, (2000) report two significant findings in their study on patient perceptions of their risk of developing diabetes-related complications. Firstly they found that patients over-estimated their risk of developing complications and secondly, that patients overestimated the reduction in risk for complications produced by intensive interventions. These results have important implications. Meltzer and Egleston (2000) suggest that overestimating the likelihood of developing complications could lead to increased levels of anxiety, the effects of which were discussed previously in the Peyrot, Rubin & Lauritzan, *et al*., (2005) study. If patients are unaware of their actual risk, they may not make informed decisions regarding risk reduction and lifestyle choices required to maintain their quality of life (Meltzer & Egelston, 2000). No full discussion of over-estimation of potential benefits of interventions was included in this study.

Overestimation has its benefits especially when perceptions of vulnerability to illness and efficacy of interventions motivate an individual to self-manage their diabetes more effectively. The absence of these components, crucially belief in the efficacy of interventions, can lead to increased levels of fear resulting in feelings of hopelessness and denial (Frijling, Robo, Keus *et al*., 2004).

Historically the treatment of diabetes has been based on the medical model with little attention paid to the psychological component of patient care, in particular, patients' self-management behaviours. With this framework, success was judged by patient compliance and adherence to treatment (Funnel, Anderson, Arnold, Barr, Donnelly, Johnson, *et al*., 1991). Since diabetes care is different from the treatment of acute illness, a new conceptual framework was required to inform the behavioural, clinical and educational approaches (Glasgow & Anderson, 1999; Funnel & Anderson, 2000; Anderson & Funnel, 2000).

Empowerment, as a conceptual framework, recognizes that individuals are responsible for the self-management of their diabetes and redefines the patient-healthcare professional relationship (Funnel & Anderson, 2000). Empowerment is defined as a process of helping people discover and develop their level of responsibility for their own lives and to gain control of their diabetes. This responsibility is required because of three crucial characteristics of the disease.

Firstly, the key choices the individual makes affecting their health and well-being are made by the person with diabetes and not by health professionals. Secondly, the consequences of these choices, for example, development of long-term complications, are attributed to the person with diabetes and not the health profession. And thirdly, individuals are in control of the daily self-management of their diabetes. They can accept or reject any advice and education from the health professionals regardless of the importance or relevance of the information provided (Fuller & Anderson, 2000).

Part of the challenge of self-managing diabetes is the feeling of not being in control. With diabetes, where the ability to self-manage determines outcomes, conflict and frustration can result, particularly when psychological health and well-being, goals and lifestyle are not taken into account.

Empowerment responds to these issues. With its roots in community and counselling psychology (Combs, Avila & Purkey, 1978; Rapport, 1987) and adult education (Wallerstein & Bernstien, 1988), it is aligned with the biopsychosocial model of disease and illness and acknowledges the whole person. The approach enables recipients to gain more power and control over their lives and to increase the number of choices available to them. With regard to diabetes, empowerment is viewed as collaboration among equals (Engel, 1977). The knowledge required to make informed decisions about diabetes falls into two categories. The first category includes knowledge about

diabetes and its treatment. The second category is based on self-awareness of needs, beliefs, values and goals and encourages people to examine the emotional, social, intellectual and spiritual elements of their lives in relation to the decision they make about self-management (Anderson, Funnell, Barr, Dedrick & Davis, 1991).

Since its introduction to the diabetes literature in 1991, empowerment has been researched in practice and controlled trials and shown to be an efficacious and practical approach to diabetes self-management and care (Funnel & Anderson, 2003). Within the healthcare setting there has been a shift towards collaborative working with patients (Glasgow, Hiss, Anderson, Friedman, Hayward, Marrero, *et al*., 2001; Williams & Zeldman, 2002; Glasgow, Funnell, Bonomi, Davis, Beckham & Wagner, 2002), patient-centred care (Renders, Valk, Griffin, Wagner, Ejik & Assendelft, 2001; Wagner, Grothaus, Sandhu, Galvin, McGregor, Artz, *et al*., 2001; Funnel & Anderson, 2003), collaborative goal setting (Funnel & Anderson, 2003; Mensing, Boucher, Cypress, Weinger, Barta, Hosey *et al*., 2000), theory-based education and increased self-management skills (Funnel & Anderson, 2003) and psychosocial issues (Lustman, Freedland, Griffith & Clouse, 2000; Rubin, 2001). Simultaneously, this has resulted in a shift away from adherence and compliance (Funnel & Anderson, 2000; Anderson & Funnel, 2000) and information transfer (Norris, Lau, Smith, Schmid & Engelgau, 2002; Barlow, Wright, Sheasby, Turner & Hainsworth, 2002).

To self-manage diabetes effectively, individuals are required to set goals, make effective decisions relevant to their lifestyle, whilst being mindful of metabolic, psychosocial and personal factors (Funnel & Anderson, 2004). Included in this process needs to be information on therapeutic options, strategies for behaviour change, problem solving and coping with the psychosocial demands of living with a chronic, long-term condition.

To allow self-management to occur, the paternalistic and maternalistic roles that the healthcare profession traditionally assumed, which were often more akin to a parent-child relationship, need to adapt to partnership working (Funnel & Anderson, 2004). This can pose challenges for the patient-health professional relationship. Control is passed to the patient and not everyone can cope with this responsibility. Some patients may feel overwhelmed. Not all professionals are able to relinquish control of the treatment process. Consultants and nurses may be required to acknowledge equality in the relationship and act as partners who are responsible to patients rather than for patients. In addition, they may find a discrepancy with the goals the patient sets for their well-being as opposed to the goals they feel would help patients' self-manage diabetes more effectively, reducing the risks of long term complications developing. For example a patient could decide that eating excessive amounts of sugary foods helps them cope with self-management whereas the consultant or nurse would be inclined to advise against this. It can also be difficult to address the negative emotions often associated with

diabetes and consultations can be lengthened if these emotions present (Levinson, Gorawara-Bhatt & Lamb, 2000).

Unfortunately Funnel and Anderson fail to account for the two main types of diabetes and the effect empowerment has on self-management of either of them. Similarly the Diabetes Empowerment Scale (Anderson, Funnel, Fitzgerald & Marrero, 2000) fails to acknowledge the difference and discusses diabetes as a single condition.

One study does investigate the effect of empowerment on self-management of Type 1 diabetes. The authors note that although educational programmes have been shown to improve metabolic control in Type 1 diabetes, the effects of interventions aimed at promoting empowerment have received little attention. Ninety participants ≤65 years of age took part over a 2-year period with 54 participants assigned to the intervention group. The study found that the educational empowerment-based intervention significantly ($p<0.005$) improved the psychosocial aspects and self-management abilities of patients with Type 1 diabetes and suggests “it is the way forward to a normal life” (Forlani, Zannoni, Tarrini, Melchionda & Marchensi, 2006, pg.2). Reported in these terms it is a sweeping and subjective suggestion difficult to quantify.

In relation to Type 2 diabetes one study assessed the empowerment score of patients in Isfahan, Iran and found that diabetes empowerment levels showed a significant relationship between variables such as level of education ($p<0.001$), gender ($p<0.007$), age ($p<0.001$) and duration of diabetes diagnosis ($p<0.001$). Furthermore ordinal regression analyses revealed that having a higher education/diploma ($p<0.005$) and optimal/borderline HbA1c ($p<0.0051$) were significant factors in empowering patients with Type 2 diabetes. The authors conclude by suggesting that patients can be empowered to self-manage their diabetes more effectively if they are informed and educated (Tol, Shojaeezadeh, Sharifirad, Alhani, & Tehrani, 2012). They fail to suggest how to empower patients whom unfortunately do not have a higher education and who struggle to control their HbA1c.

Nevertheless, empowerment has been shown to be effective in shifting the focus from blood glucose levels to acknowledgment of the person as an individual (Funnell & Anderson, 2003, 2004; Renders, Valk & Griffin *et al*., 2003). This has been achieved by using reflective listening techniques and open questioning to understand how the person is feeling, for monitoring and redefining goals, discussing how the individual perceives their diabetes and what they wish to achieve from their consultation (Heisler, Bouknight, Hayward, Smith & Kerr, 2003).

Psychological interventions should continue to develop emotional and behavioural tools and provide the education and skills to help people cope with diabetes-related issues (Vileikyte, Rubin & Leventhal, 2004). This may offer individuals an alternative to smoking, which is a well-known coping mechanism for managing stress (Erblich, Bovbjerg & Diaz, 2012).

The following section discusses the efficacy of psychology in diabetes care and gives an overview of the psychological models available to investigate behaviour change.

2.5 The Role of the Psychologist in Diabetes Care

Evidence that psychological and behavioural factors significantly affect the management and outcomes of diabetes continues to grow and as a result, psychologists are increasingly becoming an integral part of traditional diabetes care. This has been a slow process. The Minding the Gap survey reports that 85% of people in the UK with diabetes have either no access to psychological care or access to a general mental health service provider (Trigwell, Taylor, Ismail, Nicholson, Alibhai, Gosden, *et al*., 2008).

Psychologists can support patients to become more empowered by working in close partnership with them to build confidence and increase motivation, self-awareness and levels of self-efficacy. Health behaviour change is one of the

key roles of health psychology as it attempts to move individuals from negative behaviours to positive behaviours via these mechanisms. Health psychology has developed models and theories to investigate health behaviour change and to advise health care teams on strategies to incorporate psychological principles into patient care to enhance clinical outcomes. These models can be applied to smoking cessation and diabetes self-management to inform the development of complex interventions aimed at reducing long-term complications.

2.6 Biospsychosocial Models and Theoretical Frameworks

Diabetes is considered as a physiological condition. More recently, the concept of health and disease has developed from a biological model to include psychological and social factors (Sridhar & Madhu, 2002). This biopsychosocial construct (Engel, 1977) posits that disease results from a dynamic interaction between biological, psychosocial, developmental and socio-cultural factors (Sridhar, 2002).

The biopsychosocial model of health is based in part on social cognitive theory (Bandura, 1988) and implies treatment of disease processes, for example Type 2 diabetes, requires the health care team to take into account biological, psychological and social influences on patients' functioning (Halligan & Aylward, 2006).

The model suggests it is important to work with the three components in conjunction with each other. The empirical literature suggests that patient perceptions of health and threat of disease, including barriers to their social or cultural environment, can influence their willingness to engage in health-promoting or treatment behaviours, such as adherence to medication, healthy diet and physical activity (DiMatteo, Haskard & Williams, 2007).

McLaren (2004, 2006) described the model as ‘a disingenuous framework to cloak what was essentially psychosomatic illness and notes that the Journal of Psychosomatics uses the terms ‘biopsychosocial’ and ‘psychosomatic’ interchangeably. He states that whilst biology, psychology and sociology are factors of mental health together they do not equate to a scientific model. In his report ‘New Labour and the Welfare State, (2007)’, Rutherford advised that ‘the model to apply for returning people to work is the biopsychosocial one’. Without clear scientific rigor Rutherford cautioned that the model may be subject to exploitation by governments to deny the public access to health and social care. In an earlier report, Epstein and Borrell-Carrio (2005) suggest the interpretations are conflicting.

Although the biopsychosocial model does not provide a simple, testable model that gives a clear explanation of the interactions or variance accounted for by each component, it has been a useful guide for theoretical and empirical investigation. Much of the literature has identified social-cognitive

variables, for example self-efficacy in managing chronic diseases, such as Type 2 diabetes, that may influence uptake of healthy behaviours and adherence to medication (Carlson, Norman, Feltz, Franklin, Johnson & Locke, 2001; Allen, 2004). These models underpin health psychology and include the Theory of Planned Behaviour (TPB) (Ajzen, 1988), the Transtheoretical or Stages of Change Model (Prochaska & DiClemente, 1984), the Health Belief Model (HBM) (Rosenstock, 1966; Becker, 1974) and Locus of Control (Rotter, 1966).

Theoretically based frameworks lay the foundation upon which factors affecting diabetes self-management behaviours can inform psychology. Social cognition models allow for the investigation of how people make sense of themselves and others and have been used to help understand psychosis (Kuipers, Garety, Fowler, Freeman, Dunn & Babbington, 2006). The models can also be applied in an attempt to predict health behaviours.

2.6.1 Theory of Planned Behaviour (TPB)

The TPB examines the relationship between attitudes, behavioural intentions and behaviour and assesses perceived behavioural control (Ajzen, 1988). The model has been applied to the prediction of health-behaviours, including smoking, which can have serious consequences for people with diabetes, with varied outcomes. Godin, Valois, LePage and Desharnais, (1992) found the TPB to be a useful predictor of smoking behaviour and intentions in two

prospective studies. The first study was among the general population and the second was among pregnant women. Perceived behavioural control emerged as the strongest predictor of behavioural intentions in both studies, with behavioural intentions relating to smoking status at 6-month follow-up.

More recently the TPB has been used in a study to explain physical activity in an adult population with Type 1 and Type 2 diabetes. The findings added to the evidence base of the utility of the TPB in designing physical activity interventions with suggestions that the principles would be transferable to other health interventions (Plotnikoff, Lippke, Courneya, Birkett & Sigal, 2010).

Whilst the TPB has been useful in broadening the understanding of a variety of health-related behaviours, its main weakness is that it focuses on perceptions of behavioural control and not with actual behavioural control (Connor & Sparks, 2001).

2.6.2 Health Belief Model (HBM)

Central to health behaviours are health beliefs. The HBM focuses on threat perceptions and behavioural evaluation. Threat perception is associated with two beliefs, perceived susceptibility to illness and anticipated severity of the consequences of the illness. Behavioural evaluation is also associated with two distinct sets of beliefs, the efficacy of specific health behaviours and the

barriers to performing those behaviours (Rosenstock, 1966). Becker, Haefner and Maiman, (1977) later added another two constructs, cues to action and health motivation, bringing the total HBM constructs to six.

The HBM has been applied in research more often than other social cognitive models and in three main areas, health promoting (e.g. diet) and health risk (e.g. smoking) behaviours, sick role behaviours and clinical utility. Even so, there have been issues with this model. For example, applications of the HBM have not included all components in the measurement process and components are often combined under a single construct rather than measured separately (Gianetti, Reynolds & Rihen, 1985). There has also been a general failure to check the reliability and validity of the constructs, throughout the literature (Sheeran & Abraham, 1996).

The HBM was used to underpin a trial aimed at improving medication self-management in a population with co-existing diabetes and kidney disease. Although the authors claim “the major strength of this trial is that it is one of the first published studies to tackle the problem of competing co-morbidity management where consumers are required to consult with multiple health practitioners and take multiple prescribed medications”, they fail to acknowledge the utility of the HBM to predict patient outcomes (Williams, Manias & Walker, 2010, pg7). The only mention of the HBM is to advise the model was used to underpin the development of a DVD involving an

interactive psychosocial approach to motivate patients to take their medication. The study was beset with issues but did suggest that management of co-morbidities is increasing and may benefit from interventions to improve patient outcomes particularly with regard to an evidence-based approach to patient care. There was no discussion of the efficacy of the DVD on patient outcomes.

Despite the fact that Rosenstock (1974) suggested a relationship between health beliefs and psychological stages in decision-making, and the weakness highlighted in the literature, the HBM has not been re-conceptualised. This lack of evolution led to rejection of the HBM for conceptual frameworks that were developing throughout the 1980's. These included work on locus of control (Wallston & Wallston, 1982) and perceived control derived from attribution theory, which had been shown to be a determinant of health behaviour (King, 1982).

Research based on psychological theory has highlighted the importance of patients' personal beliefs regarding their illness and treatment and the impact these beliefs have on their self-management of a range of chronic illnesses, including diabetes (Petrie, Weinman, Sharpe & Buckley, 1996; Leventhal, Meyer & Nerenz, 1980). This report shows that patients' illness beliefs cluster around five dimensions:

(1) Identity: including the disease label and associated beliefs about the symptoms of the disease

(2) Timeline: beliefs about the course and duration of the disease

(3) Consequences: the effects of the disease

(4) Cause: the perceived cause(s) of the disease

(5) Cure/control: including beliefs about recovery from the illness or ability to control an existing condition (Leventhal, Meyer & Nerenz, 1980).

Beliefs have been demonstrated as central to understanding the strategies patients adopt to cope with their condition. For instance, research on illness beliefs and diabetes has indicated that patients who believe they are in control of their illness are more inclined to engage with the healthcare system to seek treatment and make positive lifestyle modifications (Hampson, Glasgow & Foster, 1995).

Furthermore, patients have beliefs about the importance of taking medication and concerns about the possible long-term effects. These beliefs have shown to be strong predictors of adherence to medication (Horne, Weinman & Hankins, 1999; Horne, 2003), which is essential if patients with diabetes are to reduce the risk of developing long-term complications and for maintaining quality of life (Cox & Gonder-Frederick, 1992; DCCTRG, 1993). Nevertheless,

a patient with positive coping strategies engaging with treatment can easily be blocked by another psychosocial dimension known as locus of control.

2.6.3 Locus of Control

Locus of Control is a construct considered important to personality (Rotter, 1966). Derived from Locus of Control of Reinforcement, it was developed to connect behavioural and cognitive psychology. Rotter suggested behaviour was directed by reinforcements or rewards and punishments. These contingent actions were thought to help identify the causes of certain behaviours and guide beliefs on the attitudes and behaviour people adopt (Rotter, 1966).

Thus, locus of control is described as a unidimensional continuum, ranging from external at one end to internal at the opposite end. A high internal locus of control indicates people believe events result from their own behaviour and actions. Conversely, a high external locus of control indicates people believe powerful others, fate, or chance determines events (Rotter, 1966).

Locus of control is the framework of social learning theory of personality (Rotter 1966), but its immediate background was developed by Rotters' students who studied two types of expectancy shifts:

typical expectancy shifts - belief that success or failure will be followed by a similar outcome

atypical expectancy shifts - belief that success or failure will not be followed by a similar outcome.

Work in this field led psychologists to suggest that people who exhibit typical expectancy shifts were more inclined to attribute outcomes to their abilities. People who exhibit atypical expectancy shifts were more inclined to attribute outcomes to chance. This was interpreted as saying that people could be divided into two specific groups, those who attribute outcomes to ability (an internal cause) compared with those who attribute outcomes to luck (an external cause) (Rotter, 1966).

Rotter (1975) cautioned that internality and externality were not an either/or typology but rather, characterized opposite ends of a spectrum. Individuals with an internal locus of control are more inclined to attribute outcomes to their own control. Conversely, individuals with an external locus of control are more inclined to attribute outcomes to external circumstances or chance. This has obvious implications for differences between internals and externals in terms of their achievement motivation, suggesting that internal locus is linked with higher levels of Need for Achievement (McClelland, 1958). Because they locate control outside of themselves, people with an external locus of control feel they have less control over their fate and tend to be more stressed and

prone to clinical depression (Benassi, Sweeney & Dufour, 1988; cited in Maltby, Day & Macaskill, 2007).

Abramson, Seligman and Teasdale (1978) introduced the concept of attributional style. This concept expands on Weiner's (1986) work, advising that a further dimension of globality-specificity should be considered alongside internality-externality and stability (Weiner, 1974). Abramson *et al.,* (1978) suggest the way people explain success and failure in their lives relates to whether they attribute these to internal or external factors, to whether factors are short-term or long-term and whether they affected all situations.

Attributional theorists originated in social psychology. They focus on ways past events influence how and why people explain actions and behaviours in the way they do. Locus of control theorists explore the differences in individuals' explanatory styles and focus on expectations of control over future events.

Weiner (1986) argues for an attributional theory of motivation and emotion and suggests thinking gives rise to feelings which guide actions. If the action has a positive impact on the individuals' feelings about themselves, they will be motivated to perform the action again. Conversely, if the action has a

negative impact on feelings about themselves, the individuals will be less inclined to repeat the action (Weiner, 2007, 2006, 1986).

The most prominent application of locus of control has been in health psychology (Wallston, Wallston & DeVellis, 1978). Furnham and Steele (1993) conducted a literature review and found scales that measure general health and scales that measure more specific health domains such as obesity and mental health. Bradley, Lewis Jennings and Ward, (1990), conducted a study of scales to measure perceived control for people with tablet-treated diabetes from which Furnham and Steele (1993) note the link between locus of control and self-management of the condition. They review reports that an internal locus of control tends to result in the patient managing his or her own treatment quite successfully (Bradley, Lewis, Jennings & Ward, 1990).

In their literature review on health locus of control, Norman and Bennett (1996) concluded some of the findings were ambiguous. In the case of jogging, Norman and Bennett report some studies found internal health locus of control to be linked to increased exercise. Nevertheless several studies found little or no relationship between exercise and internal health locus of control. With regard to the relationship between internal health locus of control and breast self-examination, weight control and preventative health behaviours the findings were inconsistent. Some studies reported a

relationship between the behaviours and locus of control whilst others did not (Norman & Bennett, 1996).

These inconsistencies led Wallston (1989, 1992) to modify social learning theory noting that health locus of control beliefs were key to performing a health behaviour but inadequate on their own. It is argued the findings may be due to the degree participants value their health and belief that their behaviour would improve their health and self-efficacy to perform the behaviour (Norman & Bennett, 1996).

Norman and Bennett (1996) highlight that powerful others health locus of control, as well as internal health locus of control, may be linked with smoking cessation. They argue that a stronger association is found when health locus of control is assessed for specific behaviour. They refer to several studies which have used health-related locus of control scales in particular areas, including smoking cessation (Georgiou & Bradley, 1992), diabetes (Ferraro, Price, Desmond & Roberts, 1987) and tablet-treated diabetes (Bradley, Lewis, Jennings & Ward, 1990). Norman and Bennett (1996) also argue that health locus of control is better at predicting health-related behaviour if studied in combination with health value, *i.e.* the value people attach to their health, providing further support for their earlier suggestion that health value is an important moderating variable in the health-locus of control relationship (Norman & Bennett, 1996).

The Smoking Locus of Control Scale (SLoCS) (Georgiou & Bradley, 1992) and the Perceived Control of Diabetes Scale (PCDS) (Bradley, 1993) were developed from previous work by Wallston, Wallston, Kaplan and Maides, (1978) on locus of control measurements and on developments in measures of attributional style (Peterson, Semel, von Baever, Abrahmson, Metalsky & Seligman, 1982). As discussed in the preceding text (pg. 41), attributional style derives from attributional theories that predict an individual's explanation for past events is more likely to influence their expectations of their future behaviour (Weiner, 1986). Locus of control scales differ as they are concerned with measuring expectations of future events.

In contrast to the views proposed by the attributional theorists, Norman and Bennett's (1996) argue in favour of health-specific locus of control measures supporting Bradley's (1985) review of the literature. The review suggests researchers have acknowledged the concept of perceived control of diabetes as important in understanding a patient's motivation to self-manage their condition. An individual signifying an internal locus of control would be expected to be more motivated to adhere to treatment and follow a demanding treatment regimen than an individual signifying an external locus of control (Bradley, 1985).

The PCDS (Bradley, 1993) attempts to measure ways in which individuals explain the short and long-term outcomes of their diabetes, and was originally

aimed at people with Type I diabetes. The scale was not only concerned with perceptions of locus of control but also with perceptions of responsibility and foreseeability and with perceptions of control by the individual's doctors and others. The rationale for subsequent modification for Type 2 diabetes was to understand individual differences in preferences for treatment regimens and differences in the degree of diabetes control achieved.

The PCDS (Bradley, 1993) was developed because of its relevance to diabetes and because generic measures were not sensitive to disease-related adjustments. Researchers recognized that notions of perceived control over diabetes are likely to be important in understanding patients' motivation to manage their diabetes. An individual with diabetes who attributes diabetes control to good or bad luck would not be expected to be as well motivated to follow a demanding treatment regimen as a person who favours an internal locus of control and attributes good blood glucose control to their own efforts (Bradley, 1985). The scales were designed to have a similar format to Peterson, Semel & von Baever *et al*.'s (1982) Attributional Style Questionnaire.

Comparison of the perceptions of control of diabetes between health care professionals and patients highlighted a bias in the professionals' perceptions, whereby they were less inclined to attribute negative outcomes to medical factors, which may have had a negative impact on the patient-health care

professional relationship. The PCDS (Bradley, 1993) has attempted to redress this discrepancy by measuring attributions and has been found to be significantly associated with HbA1c (glycated haemoglobin level), percentage ideal body weight, well-being and treatment satisfaction with Type 2 diabetes (Bradley, Lewis, Jennings & Ward, 1990).

Because the scale measures psychological processes rather than outcomes, Bradley suggests the scale is more constructive in research aimed at assessing the effectiveness of interventions such as education programmes seeking to modify perceptions of control to achieve desired health outcomes (Bradley, 2003).

In a study analyzing psychological conditions required to adopt a healthy lifestyle, the Health Locus of Control construct (HLC), was related to health-promoting behaviours in a population of healthy people. There was a positive correlation between an internal locus of control and adherence to a healthy diet. These findings demonstrate the utility of the HLC construct when investigating health behaviour (Wilczynska, Bargiel-Matusiewicz, Troc & Niebroj, 2013).

The models also provide key components on which behaviour change interventions can focus to be effective. These include beliefs, perceptions,

goal-setting, problem solving, coping strategies, perceived control and motivation.

Weiner (2007) links an internal locus of control more closely to the concept of motivation. In an example related to two students failing an important exam, Weiner describes how the first student, who fails the exam unexpectedly, feels unhappiness followed by a search for causality leading to a belief in their own lack of aptitude. Perceived lack of aptitude is an internal, stable and uncontrollable cause leading to a reduction in self-esteem, low expectancy of future success and hopelessness.

The second student also feels unhappiness. This student has had past success and attributes the failure to lack of effort. This internal, stable yet controllable cause facilitates positive motivators such as regret, guilt, hope and expectancy and motivates this student to apply more effort in the future (Weiner, 2007).

Weiner's (2007) example suggests that to change behaviour, the individual first has to be motivated. One method used in behaviour change therapies which is designed to evoke an individual's motivation is motivational interviewing (Miller & Rollnick, 2002).

2.7 Motivational Interviewing

Motivational Interviewing (MI) evolved from experience in the treatment of problem drinkers, and was first described by Miller (1983). The basic concept and approach were subsequently augmented by Miller and Rollnick (1991; 2002) in a more detailed description of clinical procedures. However, a clear definition of motivational interviewing was missing.

Miller and Rollnick's (2002) theory draws inspiration from Carl Rogers' (1951) work on non-directive counselling. The examination and resolution of ambivalence is the key principle of non-directive counselling, and the counsellor is intentionally directive in pursuing this goal (Rogers, 1951). In comparison to nondirective counselling, MI is more focused and goal-directed.

More recently, Miller and Rose (2009) have attempted to develop a theory of motivational interviewing and conclude that after three decades of research, MI is an evidence-based psychotherapeutic methodology. Miller and Rose (2009) also conclude that, in practice, MI is relatively brief and augments other treatment methods, is specifiable and applicable to a wide range of behaviour change, and is learnable by most health professionals. A testable theory of the underpinning mechanisms of MI is emerging, with measurable components that are both relational, based on the relationship between the client and the practitioner and technical, based on the skilled use of MI techniques (Miller & Rose, 2009).

A state of ambivalence is often found to be central to the individual's behaviour, which can lead to a lack of motivation. Friction can occur if ambivalence is confused with denial or resistance (Miller & Rollnick, 2002).

People struggling with addictions often recognize the risks, costs and harm associated with their behaviour and for various reasons, can be attracted to their behaviour. For example, they want to smoke and do not want to smoke. They want to change whilst simultaneously do not want to change (Miller & Rollnick, 2002).

When people get stuck in an ambivalent state, problems can persist and intensify. It is a normal part of the process of change and successfully resolving ambivalence is a key skill in effective MI.

In the quest to resolve ambivalence MI is guided by four key principles:

a. Express empathy

b. Develop discrepancy

c. Roll with resistance

d. Support self-efficacy

2.7.1 A - Express Empathy

Miller and Rollnick suggest a client-centred and empathic counselling style is one of the fundamental and defining characteristics of MI, underpinned by an attitude of acceptance by the counsellor. Acceptance is different from agreement or approval and it is suggested that acceptance of people as they are, gives them the freedom to change. Such an attitude combined with respect, builds a working therapeutic partnership that helps develop clients' self-esteem, which further promotes change. In this type of relationship, the client is not seen as uniquely pathological. Rather, their situation is understood as having become 'stuck' through understandable psychological processes (Miller & Rollnick, 2002).

2.7.2 B - Develop Discrepancy

MI is purposefully directed towards the resolution of ambivalence in the quest for change. It is aimed at getting people 'unstuck' and helping them move toward positive health behaviour change. A second general principle of MI is to create and magnify a discrepancy between present behaviour and the broader goals and values. Miller and Rollnick emphasise discrepancy is related to the importance of change and not the amount of change (Miller & Rollnick, 2002).

Discrepancy can be triggered by awareness of and dissatisfaction with the costs of an individual's present behaviour and by perceived advantages of positive behaviour change. When behaviour is seen as conflicting with important personal goals, change is more likely to occur. Many individuals seeking consultation already perceive discrepancies between what is actually happening and what they want to happen, yet are still ambivalent.

MI methodology aims to elicit awareness of discrepancy within the individual. When skillfully done, MI changes the person's perceptions of discrepancy without creating a sense of being pressured or coerced and results in the individual voicing concerns, reasons for change, self-efficacy and intentions to change (Miller & Rollnick, 2002).

2.7.3 C - Roll with Resistance

The least desirable situation in MI is for the counsellor to advocate for change while the individual argues against it. Not only is the ambivalent person unlikely to be persuaded, direct argument can and does send the person in the opposite direction. Hayley made the analogy of psychological judo whereby an attack is not met with direct opposition as in boxing but relies on using the attacker's momentum to good advantage (Hayley, 1963).

MI should not be combative. It is not about winning and losing with an opponent to be outsmarted or defeated. An individual's resistance can be reframed to generate new momentum toward behaviour change with the object in motion not a body, as Hayley suggested, but a perception. MI views resistant behaviour as an indication for the counsellor to change their approach and since it is such an interpersonal relationship, the way the counsellor responds will influence the degree to which resistance increases or diminishes (Miller & Rollnick, 2002).

2.7.4 D - Support Self-Efficacy

Self-efficacy refers to person's belief in their ability to carry out and succeed with a specific task. It is a key element in MI for change and is a reasonably good predictor of treatment outcome (Miller, 1985; Frank & Frank, 1991).

One of the goals of MI is to enhance the individuals' confidence in their capabilities to cope with barriers and to succeed in change. It asserts the client is responsible for deciding and directing their own change and assumes the ability to change is within their capabilities (Miller & Rollnick, 2002).

Motivational interviewing has been used effectively in a wide range of behavioural and health-related problems. These include alcohol and drug

misuse (Miller, Zweben & DiClemente & Rychtarik, 1994) and bulimia nervosa (Treasure & Schmidt, 1997).

Noonan and Moyers (1997) reviewed eleven clinical trials investigating a range of behavioural issues and concluded MI was an effective clinical intervention. Nine studies found MI more effective than no treatment, standard care, extended treatment or being on a waiting list before receiving the intervention. Two studies did not support MI as an effective intervention. Noonan and Moyers (1997) suggest this may be due to the individual being given advice in an authoritarian manner and the clinician not receiving adequate training. Overall, the review supports the use of MI as an effective intervention.

Dunn, DeRoo, and Rivara (2001), conducted a systematic review of twenty-nine randomized trials of brief interventions that used MI principles to change behaviour in four specific areas. These include substance misuse, smoking, HIV-risk reduction and diet and exercise. The strongest evidence for efficacy was found in alcohol and drug misuse, where MI appeared more effective for problem drinkers and improved the rate of entry and retention in intensive substance misuse treatment. In an article critiquing MI, Vansteenkiste and Sheldon, (2006) discuss the promises and limitations of MI, reporting reduced efficacy for the technique with regard to HIV risk behaviours and smoking

cessation. Whilst they fail to offer an explanation as to why this may be the case they do allude to the fact that MI is more effective if skillfully applied.

Burke, Arkowitz and Dunn (2002), reviewed twenty-six qualitative studies. The authors concluded the research supported the efficacy of MI for alcohol problems, drug addiction, hypertension, and bulimia as well as encouraging compliance in patients with diabetes. Mixed support was found for the effectiveness of MI with regard to smoking cessation, increasing physical activity and enhancing dietary adherence in patients with hyperlipidemia.

Subsequently, Burke, Arkowitz and Menchola (2003) investigated the efficacy of MI by conducting a meta-analysis of controlled clinical trials exploring substance misuse, diet and exercise, smoking cessation and HIV risk-reduction. The empirical studies and reviews were investigating adaptations of motivational interviewing (AMIs). AMIs ranged from brief advice, behaviour change counselling and motivational interviewing. Brief advice is an opportunistic situation typically lasting five to ten minutes where the practitioner takes the leading role and provides information. Behaviour change counselling can last between five and thirty minutes and involves the individual by establishing goals, building motivation for change and exchanging information. Motivational interviewing lasts between thirty and sixty minutes and is designed to build a relationship between the individual and the practitioner to resolve ambivalence, set goals and elicit change talk.

Burke, Arkowitz and Menchola (2003) found no support for the efficacy of AMIs for smoking cessation and found no studies investigating the efficacy of motivational interviewing in its original form. Treasure (2004) reported mixed results for the efficacy of MI in smoking cessation with moderate effect sizes of between 0.25 and 0.57 found in adaptations of MI.

In a more recent meta-analysis and systematic review of controlled trials exploring substance misuse, cigarette consumption, diabetes self-management and weight loss, Rubak, Sandbæk, Lauritzen and Christensen (2005) reported a significant effect of MI for combined effect estimates for body mass index, total blood cholesterol, systolic blood pressure, blood alcohol concentration and standard ethanol content. No significant effects were found for daily cigarette consumption or blood glucose control.

In addition, MI was found to have a significant and clinically relevant and equal effect on physiological (72%) and psychological (75%) diseases. Physicians and psychologists obtained an effect in approximately 80% of the studies, while other healthcare providers obtained an effect in 46% of the studies. When using MI in brief encounters of approximately 15 minutes, 64% of the studies showed an effect. These findings suggest that MI in a scientific setting outperforms traditional healthcare advice (Rubak, Sandbæk, Lauritzen & Christensen, 2005).

The authors note studies do not include epidemiological measures such as questionnaires or clinical measures such as blood pressure, blood glucose and weight and suggest that future MI research should, wherever possible, measure effect by epidemiological and physiological as well as clinical direct measures to ensure the reliability of the results.

Motivational Interviewing has been shown to be effective in some settings, including healthcare. Nevertheless it is important to appreciate that MI may not be appropriate in all situations. Miller concluded the only limitations of MI lie with the aptitude of the individuals who try to incorporate MI techniques into their therapeutic sessions (Miller, 1983), a conclusion supported by Noonan and Moyer (1997) and Vansteenkiste and Sheldon, (2006).

The expertise of the therapist or counsellor is important. However MI requires more than an adept counsellor to be effective. In relation to their work on eating disorders, Treasure and Schmidt (1997) and Treasure and Ward (1997), note that for MI to be effective there has to be an equal balance of power between the individual and the therapist, which is not always the case. The authors also advise the duration and amount of MI sessions can have an impact on the efficacy of MI techniques (Treasure & Schmidt, 1997; Treasure & Ward, 1997).

In spite of the appeal of MI, there is insufficient evidence regarding the mediating processes by which these techniques have an effect (Burke, Arkowitz & Dunn, 2002).

There are clearly mixed reviews for the efficacy of MI across a broad range of health conditions and settings (Burke, Arkowitz & Dunn, 2002; Burke, Arkowitz & Menchola, 2003; Treasure, 2004). There is also evidence to suggest the efficacy of MI is determined by the skills of the practitioner and the timeline of the intervention. A Cochrane Review of 14 randomized controlled trials between 1997 and 2008 investigating the efficacy of MI for smoking cessation found MI versus brief advice resulted in a significant increase in smoking cessation (RR 1.27; 95% CI 1.14 to 1.42) when delivered by GPs (RR 3.49; 95% CI 1.53 to 7.94) or trained counsellors (RR1.27; 95% CI 1.12 to 1.43) and when conducted in sessions lasting longer than 20 minutes ((RR 1.31; 95% CI 1.16 to 1.49). The review also found positive outcomes whether MI was delivered in a single session or over multiple sessions (Lai, Cahill, Qin & Tang, 2010).

Miller openly admits that although based on Roger's (1951) non-directive counselling technique, MI lacks a formal theoretical framework (Miller & Rose, 2009). The principles and practice of MI have mostly developed over the years from clinical practice and experience. Whilst such practical experience has helped shape MI, a unifying theoretical framework would offer the

possibility of reaching a deeper understanding of the processes involved which could help to inform future developments in MI's methodology and application.

Nonetheless, MI has been used effectively in smoking cessation programmes by ASH Scotland, NHS Scotland and extensively in health interventions by Miller and Rollnick and based on this was incorporated into this research as a tool to facilitate health behaviour change.

The roles of lifestyle and behavioural factors in patients with Type 2 diabetes, for example smoking, have been shown to contribute to poor self-management and more rapid disease progression. Changing these behaviours can reduce the risk of developing diabetes and delay the onset of long-term complications (Canga, de Irala & Vana *et al.*, 2000). To develop an intervention to address this, it is important to understand patients' perceptions of their diabetes control and of their smoking behaviour.

Health locus of control has been shown to be related to whether an individual changes their health behaviour and furthermore, to the communication style they require from the health professional. It is generally assumed that those who believe that they have control over their health will be more likely to perform a range of health promoting behaviours (Ogden, 2000).

Patient ambivalence to behaviour change is a common problem faced by health care professionals (Rollnick, Heather & Bell, 1992). The main focus of MI is directing behaviour change by helping patients to explore and resolve ambivalence about their behaviour change (Rollnick & Miller, 1994). Consultations are more successful when there is a sharing of ideas (Tuckett, Boulton & Olsen, 1985). MI appears consistent with a number of models of health behaviour including Locus of Control (Rotter, 1966).

The greatest support for the efficacy of MI applied to health behaviour change is from smoking cessation studies (Valanis, Lichenstein, Mullolly; Labuhn, Brody, Severson, *et al.*, 2001; Eammons, Hammon, Velicer, Evans & Monroe, 2001; Stotts, DiClemente & Dolan-Mullen, 2002). These findings should be interpreted with caution as they can be dependent on study quality, treatment fidelity, therapist training and publication bias and may contribute to the mixed outcomes reported in the literature (Lai, Cahill, Qin & Tang, 2010).

In a study investigating the locus of control in Type 1 and Type 2 diabetes, and the differences between patients receiving different types of care, for example, group or one-to-one intervention, the results showed patients self-managing Type 2 diabetes scored higher on the internal locus of control scale (Trento, Tomelini, Basile, Borgo, Passera, Miselli, *et al*., 2008). These findings support earlier studies. Gillibrand & Stevenson (2006) investigated the application of the extended health belief model to the experiences of young

people living with diabetes and found that high internal locus of control beliefs predicted the young person would perceive the benefits as outweighing the costs of adhering to their self-management requirements.

Similarly an investigation of adherence to treatment by patients with Type 2 diabetes found a high internal locus of control was the key predictor of health behaviours (O'Hea, Grothe, Bodenlor, Boudreaux, White & Brantley, 2005).

In light of the evidence presented in this chapter it seemed relevant to develop a study and intervention based on diabetes and smoking cessation. The initial emphasis was glycaemic control. However, mindful of the challenges of the direct approach witnessed during shadowing, it seemed appropriate to try to reframe the approach. A review of successful initiatives aimed at changing attitudes, knowledge and behaviour, reported on seven case studies from a range of topics including: HIV/AIDS initiative promoting condom use; the Scottish Smokefree public places campaign; greener transport initiatives; tobacco-counter marketing; responsible gambling; speeding campaigns and gay and lesbian mental health initiatives. The report suggests the skills gained in these initiatives are transferable to tackling the increase in alcohol consumption across the UK and that reframing the issue and social norms were integral to changing behaviour (Stead, Gordon, Holme, Moodie, Hastings & Angus, 2009).

Shaped by the literature review the following aims and research question guided the investigation.

2.8 Aims and Research Question

Primary Aims

To investigate the impact a smoking cessation intervention may have on:

1. Glycated haemoglobin levels (HbA1c)
2. Perceived Control of Diabetes in patients with Type 2 diabetes
3. Smoking Locus of Control in patients with Type 2 diabetes
4. Carbon Monoxide levels (ppm) as an indicator of cigarette use

Secondary Aims

To investigate the impact a smoking cessation intervention may have on:

1. Readiness to stop smoking (likes, dislikes, motivation and confidence)
2. Concerns about stopping smoking and remaining a smoker
3. Awareness of smoking cessation products and services
4. Knowledge of health risks associated with smoking and diabetes
5. Weight (kg)

Research Question

Does gaining control of smoking behaviours have a positive impact on glycaemic control in patients with Type 2 diabetes?

The following chapter describes the study design and methodology and introduces the Diabetes and Smoking Cessation Education Programme.

Chapter 3 - Study Design and Methodology

3.1 Study Rationale

The aim of this study was to investigate the impact of a smoking cessation psychological intervention on glycaemic control in patients with Type 2 diabetes who were regular cigarette smokers. Earlier discussions described how patients were finding it a challenge to maintain glycated haemoglobin levels within the recommended levels of 48mmol/mol (IFCC, 2008) despite regular annual reviews and additional support from the dedicated diabetes team.

This prompted the current reframing approach (Stead, *et al*., 2009) shifting the focus from glycaemic control itself to smoking cessation in an attempt to investigate whether controlling behaviour in one area of the patients life would transfer to controlling behaviour in another area of the their life.

3.2 Study Design

Drawing upon the theoretical underpinnings of quantitative research the study was a longitudinal, non-randomised, pre-post intervention. This design was chosen to broaden understanding of the impact of a smoking cessation intervention by using validated scales (Perceived Control of Diabetes Scale and Smoking Locus of Control Scale) and a minimum data set (MDS) described in more detail in section 3.6 (pg. 83). The intervention consisted of two components. The first component utilized the scales and MDS to gather

pre-intervention data, including glycated haemoglobin and carbon monoxide levels, before commencement of the Diabetes and Smoking Cessation Education Programme (DSCEP). This programme was developed by the researcher to facilitate and inform the research, based on clinical experience and best practice, and is discussed more fully in section 3.8 (pg. 95). The original study design incorporated 3, 6, 9 and 12-month follow up. None of the participants returned to the study at 3, 6 or 9-month follow-up despite reminder letters. Therefore the second component was conducted 12-months later and only utilized the PCDS, SLoCS, and elements of the MDS to gather post-intervention data. These included HbA1c and CO levels, likes and dislikes of smoking, levels of motivation and confidence to stop smoking, concerns regarding stopping smoking and remaining a smoker, awareness of smoking cessation products and services and knowledge of health risks associated with smoking and diabetes. No data were collected regarding cigarette use at this point.

3.2.1 Rationale and benefits for Quantitative Methodology

A quantitative approach was chosen in this instance in an attempt to summarise outcomes and to offer the intervention to as many participants as were willing to take part within the timeframe. This promoted reliability of the data, offering an inclusive interpretation of the research problem (Foss and Ellefsen, 2002). It also heightened confidence in the validity of the data and subsequent interpretation (Connor *et al.,* 2001). Qualitative investigation was

beyond the scope of this study and consequently led to a lack of contextual information that a mixed methodology approach may well have provided.

3.3 Participant Recruitment

Participants were recruited from patients as they attended Falkirk Royal Infirmary for their annual diabetes review. A large notice was placed at reception advising that the study was ongoing and that patients may be approached and invited to participate. Permission had previously been granted by senior diabetes consultants for the researcher to access patient case notes solely to identify which patients had Type 2 diabetes and were current cigarette smokers. This was on the understanding that the case notes would not be removed from the dedicated station within the department.

3.4 Sample Description

3.4.1 Inclusion Criteria

Participants in the study were required to be all adults over 25 years of age self-managing Type 2 diabetes and identified as regular cigarette smokers.

3.4.2 Participants

The sample comprised 29 adults with Type 2 diabetes who regularly smoked cigarettes. They were all patients of Falkirk Royal Infirmary and therefore resident within the catchment area of Falkirk District.

3.4.3 Exclusion Criteria

On the advice of the lead diabetes specialist nurse the research excluded the following: patients with Type 1 diabetes; patients newly diagnosed with Type 2 diabetes as it was felt they may need time to adjust to the condition and management of it; patients with Type 2 diabetes who had progressed to injecting insulin; and patients under the age of 25 years as they were managed in the Children and Young Peoples clinic in Stirling Royal Infirmary.

3.5 Procedure

3.5.1 Ethical Issues

The ethics application was initially submitted to the NHS Research Ethics Committee based in Ninewells Hospital, Dundee in July 2007. The Committee declined ethical approval on the grounds that there was no control group and therefore changes could not be attributed to the intervention with any certainty. An appeal was sent to Lothian Research Ethics Committee. LREC voiced the same concerns regarding the lack of a control group but nevertheless granted ethical approval in August 2007 on the following five recommendations:

- Making the language in some questions more understandable to a lay person
- Including non-English speaking participants and supporting them with the services of an interpreter

- Re-writing the participant information sheet and participant consent form to comply with the NRES format
- Explaining on the participant information sheet that the study was a research project and not part of the service evaluation undertaken by NHS Forth Valley
- Correcting the inconsistency between the application form and the participant consent form where the application form refers to the study and the consent form refers to the Diabetes and Smoking Cessation Education Programme

The application should have been presented to NHS Forth Valley Research and Development Department simultaneously. This was misunderstood and it became a follow-on application process, adding to the timeframe. In total the study took sixteen months to gain approval and involved the efforts of the researcher, diabetes consultants and academic supervisors and Dean of School at Queen Margaret University, to move it forward.

The delay meant Stirling Royal Infirmary could not accommodate the study leaving no scope to include a control group. The only availability left was a Friday morning in Falkirk Royal Infirmary. This left insufficient time to recruit participants to an intervention and control group and to run the study.

Although the main decision to exclude a control group was pragmatic, it was also considered unethical not to offer the intervention to all of the participants. This was based on concerns previously raised by Schwartz, Chesney, Irvine and Keefe, (1996). They and Freedman (1996) questioned the equity of not delivering the intervention to a no-treatment control group, saying the ethical principle is central to the protection of human research participants. This resulted from clinical research evidence gathered over a number of years demonstrating reducing psychological morbidity and prolonged survival among diabetes patients who had received a psychosocial intervention.

The research proposal was also submitted to the Psychology Ethics Panel at Queen Margaret University in November 2006, with ethical approval received in February 2007. Participants who met the inclusion criteria were treated in accordance with the British Psychological Society Guidelines for Ethical Research and Code of Conduct for treatment of participants (British Psychological Society, 2006), the Ethical Standards in Public Life (Scotland) Act (2000) and NHS Forth Valley Governance documents including the Code of Conduct. These documents acted as a guide to help ensure participants were treated respectfully with regard to consent, confidentiality and data protection, were provided with sufficient and accurate information to make an informed decision regarding participation and were debriefed on completion of data analyses.

3.5.2 Confidentiality and Informed Consent

All participants were given an identification number and data coded in order to maintain anonymity. Paperwork was also colour-coded to tell at a glance the time point it related to. For example, and ID of DSCEP/F/01/01 on white paper translated as participant 1, T1 in Falkirk. DSCEP/F/01/02 on pink paper translated as the same participant at T2. Information was stored in locked filing cabinets with access restricted to those directly involved with the study. Data gathered from the intervention were entered into the researchers' secure electronic database at Queen Margaret University and password protected.

To ensure informed consent participants were provided with a written information letter (Appendix A, pg. 174) outlining the study and were encouraged to ask questions. They were informed of their right to withdraw at any time. All participants provided written consent (Appendix B, pg. 177) and agreed to a letter being sent to their GP informing of their participation in the study (Appendix C, pg. 178). The Participant Information Letter and Participant Consent Form were developed in accordance with the Data Protection Act (1988) and BPS Code of Ethics (2009) and with guidance from academic supervisors at Queen Margaret University.

3.6 Description of Primary Outcome Measures

3.6.1 Glycated Haemoglobin Levels (HbA1c)

People with diabetes are encouraged to monitor their blood glucose levels at various intervals throughout the day using the finger-prick test. A blood glucose monitor pops a needle into the end of the finger drawing a droplet of blood. The droplet is monitored by the device producing a number in percentages, which the individual records either on the disc provided or in a booklet. This type of monitoring aids diabetes self-management on a day-to-day basis at home.

Blood glucose levels can fluctuate minute to minute therefore a more comprehensive measure is that of HbA1c since it changes slowly. This is done in a clinical setting and can reveal how high glycated haemoglobin levels have been over the past 2 – 3 months. The recommended levels are 6.5%-7.5% (48 -53mmol/mol).

HbA1c is the result of glucose in the blood fastening irreversibly to a specific part of the haemoglobin found in red blood cells and circulates for the lifespan of the cell it has bonded to. There is a correlation between the two since higher glucose levels result in higher HbA1c levels. As HbA1c increases, so does the risk of microvascular and macrovascular complications of diabetes (American Diabetes Association, 2009). Regular clinical monitoring of HbA1c can highlight an individual's glucose control over a set period of time, draw attention to their level of risk and emphasize their response to changes in

treatment regimen. The process also allows HbA1c levels to be set for the individual and treatment adjusted to facilitate this.

Nicotine is an appetite suppressant and when smoking reduction or cessation is achieved, appetite can return. In addition, smoke inhaled into the mouth creates substances that coat the tongue, suppressing the sense of taste. This too can return. An increased appetite combined with a renewed sense of taste is challenging when trying to stop smoking and can often lead to weight gain, discussed more fully in Section 3.7.7, (pg 94). These measures were recorded on the Minimum Data Set (Appendix D, pg 179).

3.6.2 Perceived Control of Diabetes Scale (PCDS)

The Perceived Control of Diabetes Scale (Bradley, 1993) (Appendix E, pg. 183), measures patient perceptions of their diabetes control based on past events. Bradley, Lewis, Jennings and Ward, (1990) applied Wallstons' typology (Wallston & Wallston, 1982) to the responses of a Sheffield sample of tablet-treated patients completing the PCDS. The sample provided the data for the psychometric analyses of the scales and for the application of Wallstons' typology. The data also provides support for the validity of the scales. The alpha coefficients reported for this study are consistent with the findings from previous studies (Bradley, 2003).

The scale includes six scenarios:

- Imagine that you have recently become unacceptably overweight. Write down the single most likely cause of becoming overweight

- Imagine that for several days you have found high levels of sugar when you tested your blood or urine. Write down the single most likely cause of the high sugar levels

- Imagine that you have been able to keep your weight at an acceptable level for a period of several weeks and you have felt fit and well. Write down the single most likely cause of this period of good weight control and general sense of well-being

- Imagine you have successfully avoided the complications of diabetes such as problems with your feet. Write down the single most likely cause of avoidance of diabetic complications such as problems with your feet

- Imagine you have reduced your weight to a satisfactory level after a period when you gained too much weight. Write down the single most likely cause of this weight reduction

- Imagine you have managed your diabetes successfully, living life as you wished while also keeping your glucose (sugar) levels under control. Write down this single most likely cause of managing your diabetes successfully

Each scenario includes seven subscales:

- Internality - a measure of the extent to which a participant perceives that they are in control of their diabetes

- Treatment - examines whether the participant perceives aspects of their diabetes to be due to treatment they have been recommended by their doctor
- Externality - describes an external locus of control and is a measure of the extent to which a participant perceives their diabetes control is in the hands of significant others or circumstances other than themselves
- Chance - examines whether the participant perceives aspects of their diabetes to be due to chance, luck or fate
- Patient Control - examines participant's perception of their diabetes control
- Doctor Control - examines whether the participant perceives their diabetes to be under the control of their doctor
- Foreseeablilty - examines whether the participant has the insight to predict aspects of their diabetes

Ratings for each subscale are summed across all the scenarios to obtain subscale total scores, for example, Internality (Scenario 1) + Internality (Scenario 2) + Internality (Scenario 3), etc. The six scores from the six scenarios give a possible range of scores from 0 to 36, where higher scores give greater weight to Internality, Treatment, Externality, Chance, Patient Control, Doctor Control and Foreseeability.

3.6.3 Smoking Locus of Control Scale (SLoCS)

The Smoking Locus of Control Scale (Gerogiou & Bradley, 1992) (Appendix F, pg. 189) refers to expectations of control over future events. The SLoCS asks eleven questions to be answered by circling the responses: strongly disagree, moderately disagree, slightly disagree, slightly agree, moderately agree and strongly agree. The even numbered questions measure the construct of Internality and the odd numbered questions measure the construct of Externality over a continuum. Reliability for the scale had been demonstrated in earlier work by Georgiou and Bradley (1992) and informed the development of the Multidimensional Locus of Control scale (Wallston, Wallston & DeVellis, 1978).

The questionnaire asked participants 11 questions and scored them on a six-point rating scale:

0 = Strongly Disagree

1 = Moderately Disagree

2 = Slightly Disagree

3 = Slightly Agree

4 = Moderately Agree

5 = Strongly Agree.

Questions 1, 3, 5, 7, 9 and 11 measured Externality and questions 2, 4, 6, 8 and 10 measured Internality. Scores ranged from 0 – 55 in total, 0 – 30 for

Externality and 0 – 25 for Internality. An increase in scores along the Internality/ Externality continuum between baseline and 12-month follow-up indicates a change in locus of control for smoking behaviours.

3.6.3a Internality

The Internality subscale measures an individual's tendency to believe that they are in control of their smoking behaviour. Evidence suggests that those with an internal locus of control are more inclined to engage with health promoting behaviour, adhere to treatment and take part in interventions (Maltby, Day & Macaskill, 2007).

3.6.3b Externality

The externality subscale measures an individual's tendency to believe that significant others, not themselves, are in control of their smoking behaviours, for example, health professionals, family and friends. Evidence suggests that individuals with an external locus of control are more likely to engage with negative health behaviours, are less inclined to adhere to treatment regimens and medication and engage with health interventions (Maltby, Day & Macaskill, 2007).

3.6.4 Carbon Monoxide Monitoring

Smoking status was validated using a carbon monoxide (CO) monitor (Bedfont Pico+ Smokerlyser) and recorded on the MDS (Appendix D, pg 179).

The Smokerlyser is designed as a simple screening test for cigarette use, giving an instant reading of CO levels in both parts-per-million (ppm) and percentages. Participants were asked to take a deep breath and hold it for 10 seconds before blowing hard into the monitor on the third beep. The CO breath test will give the same results as a carboxyhaemoglobin blood test, is much less invasive and can be used by non-medical personnel. It also gives an immediate result which is beneficial to the patient. CO monitoring has been shown to be an effective tool in predicting smoking habits and motivating people to maintain their quit attempt. The process helps the person to quit by providing visible proof of damaging CO levels and charting their progress during cessation therapy (Low, Ong & Tan, 2004). CO testing is mandatory in the smoking cessation clinics in Forth Valley.

3.7 Description of Secondary Outcome Measures

3.7.1 Scottish Smoking Cessation Minimum Data Set (MDS)

Information including smoking status, smoking history and smoking patterns was recorded on the Scottish Smoking Cessation Minimum Data Set (MDS) (Appendix D, pg. 179) at baseline and 12-month follow-up. The MDS was developed by Partnership Action on Tobacco and Health (PATH, 2010) which is a partnership of ASH Scotland, NHS Scotland and the Scottish Government, to capture and monitor data relevant to cessation attempts across Scotland.

A semi-structured interview captured the remainder of the information using motivational interviewing techniques and recorded the following information:

- Tobacco use
- Readiness to stop smoking including likes, dislikes and levels of motivation and confidence to stop smokinbg
- Concerns regarding stopping smoking and remaining a smoker
- Awareness of smoking cessation products and services
- Knowledge of the health risks associated with smoking and diabetes

3.7.2 Tobacco Use

The Fragerstrom Small Test for Nicotine Dependence (Heatherton, Kozlowski, Frecker & Fragerstrom, 1991) (Appendix G, pg. 191), was used as a baseline measure in an attempt to gauge participant levels of nicotine addiction. A more comprehensive test is available that attempts to determine whether the addiction is psychological, pharmacological or behavioural. The small test was sufficient for this purpose and helped in the discussion regarding appropriate pharmacotherapy. The scores range from 1-10 with 1 indicating lower levels of addiction and 10 indicating higher levels of addiction. For example, smoking more often in the mornings indicates a higher level of addiction and may warrant a nicotine replacement product with higher nicotine content. The items and scoring mechanism are explained more fully in Appendix G (pg. 191) (Heatherton, Kozlowski, Frecker & Fragerstrom, 1991; West, 2004). The following items were measured at baseline:

- time to first cigarette on waking
- how easy/hard it would be to abstain for one day
- hardest cigarette to give up
- do you smoke more during the morning
- do you need to smoke if confined to bed
- do you wake during the night to smoke

3.7.3 Readiness to Stop Smoking

Rollnick, Mason and Butler (2005) believe that readiness is a useful starting point from which to understand patient motivation to change behaviour and that the concepts of importance and confidence help to explain a patient's level of motivation or readiness to change. For example, if participants rated themselves as 1 on the motivation and confidence rating scales, they were asked what they thought would need to happen to help them increase their levels.

3.7.3a Likes and Dislikes of Smoking Behaviour

These questions were added to the MDS (Appendix D, pg. 179) to record what the participants liked and disliked about their smoking behaviour. It was anticipated that likes would outweigh dislikes at baseline but that this would change post-intervention with participants recording more dislikes at the end-point.

3.7.3b Motivation and Confidence to Stop Smoking

Motivation and confidence appear inextricably linked in relation to stopping smoking (Miller & Rose, 2009) therefore it was important to measure both levels. Smoking cessation depends on the balance between the person's motivation to stop smoking and their confidence to complete the task. Motivation is important because strategies to assist with smoking cessation will not work in people who are not highly motivated. Heavy smokers may show low motivation because they lack confidence in their ability to stop smoking. Equally lighter smokers may show low motivation because they believe they can stop anytime they choose (West, 2004). They are perhaps more confident. Motivation to stop smoking can vary considerably and be strongly influenced by environment. This last point was important to remember as it could impact the outcome of the study.

This part of the intervention focused on readiness to change behaviour and asked participants what they liked about smoking and what they disliked about it. This information was recorded qualitatively and recoded in SPSS 17 to be analyzed quantitatively. With regard to likes, 'relaxes me' was recoded to =1, 'social activity' was recoded to =2, 'me time' was recoded to =3, 'ice-breaker' was recoded to =4, 'turn to in crisis' was recoded to =5, 'only pleasure' was recoded to = 6 and 'like the taste and feel' was recoded to =7. In the case of dislikes, cost was recoded as =1, smell was recoded as =2 and risk to health was recoded as =3. Participants were asked to rate their motivation to stop smoking and their confidence to stop smoking on two separate rating scales

of 1 - 10 (1 = not at all motivated/confident to stop smoking, 10 = fully motivated/confident to stop smoking).

3.7.4 Concerns about Smoking and Stopping Smoking

Participants were asked to discuss any concerns they had about remaining a smoker and also concerns they may have about stopping smoking and staying stopped. These items were recorded qualitatively and recoded in SPSS 17 to be analyzed quantitatively. For concerns about smoking 'cost' was recoded to =1. For concerns about stopping smoking 'mood swings' was recoded to =1, 'no concerns' was recoded to =2 and 'weight gain' was recoded to =3.

3.7.5 Awareness of Smoking Cessation Products and Services

As this was a smoking cessation intervention it was appropriate to ascertain participants' knowledge of smoking cessation products and services available to them to aid a quit attempt. At baseline they were asked to name all of the products they were aware of and to identify local or national smoking cessation services, for example, clinics, Smokeline. Although this study was not a test of memory, these questions were asked again at 12-month follow-up to ensure participants had retained information on the broad range of smoking cessation products and services available. It was also an opportunity to introduce developments in both areas, such as Champix, e-cigarettes and vapourisers.

3.7.6 Knowledge of Health Risks Associated with Smoking and Diabetes

In order for the researcher to gain an understanding of participants' awareness of the health risks associated with diabetes and smoking, a section was added to the minimum data set to capture this information. This question was asked at baseline and 12-month follow-up to ensure participants were still aware of the implications and potential long-term complications of smoking with diabetes.

3.7.7 Weight Gain and Diabetes

Weight gain for someone self-managing diabetes can be problematic. It can alter the body's metabolism and ability to process sugars and fats. This can have a negative impact and increase the risk of developing long-term complications such as poor circulation and heart disease. It can also lead to progression from self-managing diabetes through diet and exercise to relying on insulin. Weight gain can also lead to fluctuations in HbA1c, which is particularly harmful.

Since weight and HbA1c measuring were beyond the scope of this study, levels were recorded retrospectively on the MDS from participant's case notes. Weight was recorded in % normal immediately after the intervention as BMI measurement was beyond the scope of this study. HbA1c was provided by the lead diabetes specialist nurse when the results were returned from the laboratory, approximately 3-4 weeks after the intervention.

3.8 Diabetes and Smoking Cessation Education Programme (DSCEP)

So called because it was initially designed to be delivered at four time-points over a 12-month period. This proved problematic and will be discussed more fully in chapter 4.

Prior to the DSCEP there was no education programme or smoking cessation intervention that was specifically tailored to, or addressed the needs of, individuals with diabetes in Forth Valley. This is despite the fact that access to specialist smoking cessation advice has been shown to significantly reduce the prevalence of smoking (West & Owen, 2012; Simpson, Hippisley-Cox & Sheikh, 2010) and that NICE (2008) encourages behaviour change interventions for smokers.

Using motivational interviewing techniques, the DSCEP facilitated a discussion on the individual's smoking history and smoking patterns, for example, daily cigarette consumption, age when started smoking, time to first cigarette on waking, and smoking in relation to self-managing diabetes and potential long-term complications. Aligned with behaviour change techniques, this discussion helped build rapport and was followed by the education programme. This provided participants with information and literature on smoking cessation techniques, products and services, described in more detail in section 3.8.2 (pg. 97) and focused on the risk to health of continued smoking with Type 2 diabetes. It also discussed the implications of weight gain, which is common in stopping smoking.

The DSCEP attempted to motivate patients to stop smoking and to self-manage their glycated haemoglobin levels more effectively (Michie, Hyder, Walia & West, 2011a; Michie, van Stralen & West, 2011b) and anticipated that gaining control of smoking behaviours would be a skill set participants could transfer to controlling glycated haemoglobin levels.

To guide the DSCEP the researcher used the Intervention Method during Consultation (Rollnick, Butler & Stott, 1977) discussed in the following section.

3.8.1 Intervention Method during Consultation

The Intervention Method during Consultation technique (Rollnick, Butler and Stott, 1977) (Appendix H, pg. 193), was adopted from their paper on helping smokers make decisions. The technique is based on three phases:

- Phase I – quick assessment, building rapport, measure motivation and confidence on scale of 1-10
- Phase II – patient identifies problems and solutions, question participant on how to move them from low levels of motivation and confidence to higher levels, useful strategies (discuss likes, dislikes and health risks)
- Phase III – patients set manageable goals and follow-up,

All three phases are based on discussion using motivational interviewing techniques.

3.8.2 Materials Used to Support DSECP

A leaflet was developed in text and pictorial format to illustrate the health risks of smoking with diabetes (Appendix I, pg. 194). ASH Scotland fact sheet 23, 'Smoking and Diabetes', highlights the risks associated with diabetes and smoking (Appendix J, pg. 201). ASH fact sheet 11, 'What happens when you stop smoking', discusses what people may experience in terms of withdrawal and recovery, when they stop smoking (Appendix K, pg. 207).

A list of pharmacotherapies was provided to give participants information on a range of products available to help them stop smoking, ‘NRT, Zyban & Champix Information fact sheet (Appendix L, pg. 212). This was supported with information on techniques to stop smoking, NHS 'How to Stop Smoking and stay stopped' booklet (Appendix M, pg. 220). A leaflet describing the local smoking cessation support available was also provided, NHS leaflet 'Ready to stop smoking? Where to find help near you!' (Appendix N, pg. 220).

On completion of the study and data analyses, participants received a debrief letter advising of the study and its outcomes (Appendix O, pg. 221).

3.9 Summary of the procedure

Patients were identified as having Type 2 diabetes and smoking cigarettes regularly from their case notes. They were approached in reception while waiting for their annual diabetes review and given an introduction and information letter describing the study. On agreeing to participate and before the intervention began patients were again asked if they had read the Information Letter and fully understood the study requirements. On confirmation of this they were asked to sign and date the Consent Form. At the end of the intervention a letter was sent to the participants' GP advising of their involvement in the study.

During the discussion with the participant the researcher populated the SLoCS and PCDS with participant responses to each question in turn. This was followed by population of the MDS with demographic and smoking related information.

Using motivational interviewing techniques and Phase I of the 'Intervention Method during Consultation' (Appendix H, pg. 193) for guidance (Rollnick, Butler & Stott, (1977), a discussion followed around the scores participants gave themselves for confidence and motivation to stop smoking. Phase II asked what would need to happen to move the participant to a higher score and to say what could work in order to achieve this. This phase also highlighted useful strategies for keeping the discussion moving and included health risks, services and products. Phase III encouraged participants to set

manageable goals related to stopping smoking and asked what the facilitator could do to help the participant achieve these goals.

At the end of the intervention participants were provided with supporting literature for reference.

At 12-month follow-up the SLoCS, PCDS and MDS were completed for comparison. Participants were thanked for taking part in the study and advised that, on completion of the data analyses, they would be sent a debrief letter outlining the study rationale and findings.

3.10 Statistical Analysis

Data were analysed in SPSS 17 using one-way repeated measures ANOVA, within−factors and included *post-hoc* analysis with Bonferroni adjustment, reducing the likelihood of a Type 1 error arising. This methodology was chosen in line with the original study design whereby it was anticipated repeated measures data would be collected across the five time points. Nine participants returned at 6-month follow-up. These data were excluded from the final analyses on the advice of academic supervisors. The study concentrated on baseline (T1) and 12-month follow-up (T2) data and reported Wilks' Lambda and the associated probability value. Wilks' Lambda was chosen as it is the most commonly reported statistic (Pallant, 2010).

The non-parametric equivalent of the one-way repeated measures ANOVA is the Friedman Test. No non-parametric analyses were run despite them being less stringent as they tend to be less sensitive and can fail to detect differences between conditions that actually exist (Pallant, 2010).

Using partial eta squared, the study aimed for 90% power, and an alpha level of 0.05. A medium effect size, ES= 0.3 was selected (Cohen, 1992). To achieve this required twenty-nine participants (n=29).

Assuming an average attrition rate of 50%, (Bijleveld & van der Kamp, 1998) the total number of participants required was forty-five (n=45). Thirty-one (n=31) participants entered and completed the study. This was perhaps due to the nature of the clinic since patients who diligently attended appointments tended to return at 12-months for their annual review and subsequent intervention follow-up.

With no control group differences cannot conclusively be attributed to the intervention (National Centre for Technology Innovation, 2007). The following chapter presents the findings of the study.

Chapter 4 – Results

This chapter begins by presenting the descriptive statistics and follows with the outcomes of the primary and secondary analyses.

4.1 Descriptive Statistics

Thirty-one participants (n=31) took part at T1 and completed at T2. Participants were 14 males (45%) and 17 females (54%). Ages ranged from 25–81 years with a mean age of 51.84 years. None were educated beyond secondary level and all self-managed their diabetes with diet and exercise or were tablet-treated. Demographic data is presented in Table 2.

Table 2: Participant demographic data at T1

Demographic Data	n =	%
Participants	31	100
Male	14	45
Female	17	55
Ethnic Origin		
White Scottish	31	100
Education Level		
Secondary	31	100
Employment Status		
Full-time	13	42
Part-time	6	19
Retired	8	26
Unemployed	4	13
Attrition		
Completed at T1	31	100
Completed at T2	29	93

N= Number of participants

4.2 Primary Outcomes

4.2.1 Glycated Haemoglobin (HbA1c)

HbA1c means and standard deviations are presented in Table 3. As these measurements were beyond the scope of this study HbA1c was recorded retrospectively from participants' case notes.

There were significant effects between T1 and T2 for HbA1c, Wilks' Lambda = .50, F (1, 30) = 30.80, p<0.0005, multivariate partial eta squared = .50.

Table 3: Mean and Standard Deviation for HbA1c (mmol/mol) pre and post smoking cessation intervention (n=31)

Outcome Measure	T1 Mean (SD)	T2 Mean (SD)
HbA1c	10.15 (2.42)	8.80 (1.52)

4.2.2 Perceived Control of Diabetes Scale

The PCDS (Bradley, 1993) is comprised of seven subscales applied to predict behaviour changes between time points. The subscales are Internality, Treatment, Externality, Chance, Patient Control, Doctor Control and Foreseeability. The means and standard deviations are reported in Table 4. The alpha coefficients for these scales are well below the generally accepted level for internal consistency. The closer the coefficient is to 1 the greater the internal consistency of the items in the scale (Gliem & Gliem, 2003). This

contradicts earlier guidance by Kline (1986) who suggests the minimum ideal coefficient for a tablet-treated Type 2 sample is 0.2. Bradley *et al.,* (1990) previously reported coefficients of 0.16 and explained the low item-total correlation demonstrated the degree of control patients felt over one aspect of their diabetes bore little resemblance to control they felt they had over other aspects of their diabetes management.

Table 4: Means and Standard Deviations for 7 subscales of Perceived Control of Diabetes Scale pre and post smoking cessation intervention (n=31)

Outcome Measure	T1 Means (SD)	T2 Means (SD)	Cronbach Alpha
Internality	20.65 (3.39)	23.23 (2.77)	0.24
Treatment	22.00 (6.36)	30.32 (6.77)	0.11
Externality	16.84 (4.59)	14.84 (5.87)	0.21
Chance	14.44 (4.18)	11.88 (2.33)	0.47
Patient Control	21.81 (4.99)	23.65 (2.65)	0.07
Doctor Control	15.90 (3.55)	12.52 (1.98)	0.32
Foreseeability	20.90 (4.40)	23.13 (2.69)	0.24

4.2.2a Internality

'To what extent was the cause due to something about you?'

There was a statistically significant change in perceptions of internality between T1 and T2 with participants demonstrating an increase in internal locus of control, Wilks Lambda = 0.74, $F (1, 30) = 10.68$, $p < 0.003$), multivariate partial eta squared = 0.26.

4.2.2b Treatment

'To what extent was the cause due to treatment recommended by your doctor?'

There was a statistically significant change in perceptions of treatment between T1 and T2, Wilks Lambda = 0.46, F (1, 30) = 34.96, $p < 0.0005$), multivariate partial eta squared = 0.54.

4.2.2c Externality

'To what extent was the cause something to do with other people or circumstances?'

Following a shift in Internality, there may be an expectation of a shift in Externality. There is a difference in the Externality means in the expected direction, suggesting that participants are demonstrating a decrease in external locus of control. The shift is not statistically significant.

4.2.2d Chance

'To what extent was the cause due to chance?'

There was a statistically significant change in perceptions of behavioural control between baseline and 12-month follow-up, Wilks Lambda = 0.74, F (1, 30) = 10.63, $p < 0.003$, multivariate partial eta squared = 0.26.

4.2.2e Patient Control

'To what extent was the cause controllable by you?'

No statistically significant effects were found.

4.2.2f Doctor Control

'To what extent was the cause controllable by your doctor?'

There was a statistically significant change in perceptions of behaviour being under doctor control between baseline and 12-month follow-up, Wilks Lambda = 0.48, $F(1, 30) = 32.99$, $p < 0.0005$), multivariate partial eta squared = 0.52.

4.2.2g Foreseeability

'To what extent do you think you could have foreseen the cause of the high sugar levels?'

No statistically significant effects were found.

4.2.3 Smoking Locus of Control Scale

The SLoCS (Georgiou & Bradley, 1992) comprises two subscales, externality and internality. Questions 1, 3, 5, 7, 9 and 11 measured Externality and questions 2, 4, 6, 8 and 10 measured Internality. An increase in scores along the Externality- Internality continuum between T1 and T2 indicates a change in locus of control for smoking behaviours. Means and standard deviations for the External and Internal subscales are presented in Table 5:

Table 5: Means and Standard Deviations for Smoking Locus of Control Subscales pre and post smoking cessation intervention (n=31)

Outcome Measure	T1 Means (SD)	T2 Means (SD)	Cronbach Alpha
External	16.29 (3.62)	16.48 (2.91)	0.57
Internal	15.42 (3.28)	18.84 (3.11)	0.52

4.2.3a Internality

There are significant changes in participants internal locus of control between baseline and 12-month follow-up Wilks Lambda = 0.58, F (1, 30) = 22.03, p < 0.0005), multivariate partial eta squared = 0.42.

4.2.3b Externality

There were no statistically significant effects on the Externality subscale.

4.2.4 Carbon Monoxide (CO) Levels

Positive effects were found for CO, Wilks Lambda = .36, F (1, 30) = 54.39, p<.0005, multivariate partial eta squared = .65. The results showed lower CO levels at T2. Means and standard deviations are presented in Table 6.

Table 6: Mean and Standard Deviations for CO levels (in ppm) (n=31)

Outcome Measure	T1 Means (SD)	T2 Means (SD)
CO	19.97 (6.25)	12.77 (3.98)

4.3 Secondary Outcomes

4.3.1 Tobacco Use

The results for Tobacco Use are presented in Table 7. Fourteen participants (43.8%) smoke their first cigarette within five minutes of waking. Thirteen participants (42%) smoke between 11-20 cigarettes per day and 2 participants (7%) smoke more than 31 per day. Nineteen participants (61%) said it would be hard or very hard to abstain from smoking for a whole day while 11 (35%) thought it would be easy or very easy. 28 participants (91%) do not waken during the night to smoke cigarettes and 21 (69%) do not smoke more in the morning. When asked what would be the hardest cigarette(s) to give up, 20 (62%) said it would be the first of the day. If confined to bed, 18 participants (58%) reported having to smoke in bed. When asked if they would find it difficult not smoking in a restricted area, 25 (81%) said they would not. This contradicts previous findings where participants indicate a high level of nicotine dependence (Heatherton, Kozlowski, Frecker & Fragerstrom, 1991).

Table 7: Minimum Dataset (MDS) of Smoking Patterns and History at T1.

MDS Questions		T1	(%)
When do you smoke your first	5	14	(45)
cigarette after waking? (mins)	10-15	4	(13)
	15-60	13	(42)
Average number cigarettes	1-10	7	(22)
smoked per day?	11-20	13	(42)
	21-30	9	(29)
	31+	2	(7)
How easy/hard is it to abstain	very easy	4	(13)
for a full day	easy	7	(23)
	hard	11	(36)
	very hard	8	(25)
	don't know	1	(3)
Do you wake in the night to smoke?	yes	3	(9)
	no	28	(91)
Do you smoke more in the morning?	yes	10	(31)
	no	21	(69)
What is your hardest cigarette	first one	20	(64)
to give up?	after dinner	6	(19)
	last one	2	(6)
	don't know	3	(9)
Would you need to smoke if	yes	18	(58)
confined to bed?	no	13	(42)
What age did you start smoking? (yrs)	10-15	3	(10)
	16-20	23	(74)
	21+	5	(16)
Is it difficult not smoking in a	yes	6	(19)
restricted area?	no	25	(81)

Note. N = Number of participants at T1

4.3.2 Readiness to Stop Smoking

The study measured 'likes' and 'dislikes' of smoking behaviour and levels of motivation and levels of confidence to stop smoking. The means and standard deviations are reported in Table 8.

Table 8: Means and Standard Deviations for number of likes and dislikes of smoking identified by participants and levels of motivation and confidence to stop smoking (on rating scale of 1-10) (n=31)

Readiness	T1 Means (SD)	T2 Means (SD)
Likes	4.74 (2.19)	4.64 (1.30)
Dislikes	2.81 (2.29)	4.23 (2.47)
Motivation	3.81 (2.19)	6.29 (2.56)
Confidence	3.23 (2.32)	5.10 (2.48)

4.3.2a Likes of Smoking

Participants were asked directly, *"what do you like about smoking?"* In all cases, participants advised that they had never been asked this question before or had never given any thought to what they liked about smoking cigarettes.

Responses included:

- It relaxes me
- It is a social activity among friends
- It gives me 'me' time
- It acts as an ice-breaker when in the company of strangers
- It is something I turn to in times of crisis
- It is my only pleasure
- I like the taste and the feel of cigarettes

At T2 many of the participants reported that this had changed. They advised that they did not like smoking very much after all and believed they smoked out of habit or nicotine addiction. The effect was not statistically significant.

4.3.3b Dislikes of Smoking

Participants were asked directly, "*what do you dislike about smoking?",* and responded with the following:

- Cost
- Smell
- Risk to health

At T1, the response in all cases was cost and smell. Risk to health was reported last in all cases. This changed at T2 with the majority of participants reporting that they disliked everything associated with their smoking behaviour.

'Dislikes' of smoking behaviour reported significant effects between time points, Wilks Lambda = .74, F (1, 30) = 10.55, p<.003, multivariate partial eta squared = .26.

4.3.3c Motivation to Stop Smoking

Participants were asked to rate their level of motivation to stop smoking on a 10-point rating scale (1=not motivated at all, 10=highly motivated). Levels increased significantly in a positive direction between T1 and T2, Wilks Lambda = .50, F (1, 30) = 30.24, p<.0005, multivariate partial eta squared = .50.

4.3.3d Confidence to Stop Smoking

Participants were asked to rate their level of confidence to stop smoking on a 10-point rating scale (1= not at all confident, 10= highly confident). There were also positive changes in levels of confidence to stop smoking between the time points, Wilks Lambda = .66, F (1, 30) = 15.69, p<.0005, multivariate partial eta squared = .34.

4.3.4 Concerns about Smoking and Stopping Smoking

4.3.4a Smoking

Participants were asked directly, "*what concerns you about remaining a smoker?*" Concerns expressed were the cost and health risks. In almost all cases participants were concerned with weight gain and mood swings, often associated with stopping smoking. With regard to concerns about remaining a smoker, there were no significant effects between T1 and T2.

4.3.4b Stopping Smoking

Participants were asked directly, *"what concerns you about stopping smoking?"* Responses included: mood swings, nothing and weight gain. At T2 the responses had not changed but the levels to which they were a concern had changed significantly, Wilks Lambda = .79, F (1, 30) = 8.05, p<.008, multivariate partial eta squared = .21. The means and standard deviations are reported in Table 9:

Table 9: Means and Standard Deviations for number of concerns identified by participants about smoking and stopping smoking pre and post smoking cessation intervention (n=31)

Concerns	T1 Means (SD)	T2 Means (SD)
Smoking	7.26 (2.44)	5.58 (2.14)
Stopping	4.13 (2.46)	2.84 (1.97

4.3.5 Awareness of Smoking Cessation Products and Services

At T1 participants were asked if health care professionals had discussed smoking in relation to their diabetes with them previously. Thirteen participants (41%) advised they had not. The question was asked again at T2 with statistically significant effects. Participants were aware of smoking cessation pharmacotherapy and services and gave multiple answers. A summary of product and service awareness is presented in Table 10.

The differences in awareness of smoking cessation products between T1 and T2 were statistically significant with participants able to recall most of the products available. Results show that differences between conditions are unlikely to have arisen by sampling error ($F(1, 30) = 85.2$, $p<0.0005$); an overall effect size of 0.759 shows a variation of approximately 76%.

Table 10: Awareness of Smoking Cessation Products and Services demonstrated by participants

Awareness	T1 (n=31)	%	T2 (n=31)	%
Products				
NRT Patch	29	94	31	100
NRT Gum	11	35	31	100
NRT Inhalator	8	26	25	81
NRT Lozenge	1	3	18	58
NRT Microtab	3	10	10	32
NRT Nasal Spray	0	0	17	55
Zyban	0	0	31	100*
Champix	1	3	31	100*
Services				
Hospital	6	19	31	100
Drop-in clinic	7	22	31	100
GP	10	31	31	100
Pharmacy	1	3	31	100
Smokeline	5	16	24	77
No knowledge	8	26	0	0

*Although the participants could not identify Zyban and Champix by name, they did recall that tablet products were available.

Similarly, awareness of smoking cessation services also resulted in statistically significant effects. Results show that differences between conditions are unlikely to have arisen by sampling error ($F(1, 30) = 41.72$, $p<0.0005$); an overall effect size of 0.607 shows an approximate variation of 61%.

Means for awareness of products and services have increased in a positive direction and are presented in Table 11.

Table 11: Means and Standard Deviations for Awareness of Smoking Cessation Products and Services identified by participants

Awareness	T1 Means (SD)	T2 Means (SD)
Products	7.86 (5.38)	17.00 (0.00)
Services	5.36 (3.13)	8.86 (0.54)

4.3.6 Associated Health Risks

At T1 participants were asked to list the health risks associated with smoking and diabetes. The responses showed that:

- 25 participants believed themselves to be at risk of lung cancer
- 7 participants were aware of the risk to circulation
- 11 participants were aware of the risk of CHD and CVD
- 4 participants were aware of the risk of stroke

None of the participants were aware of the risk of:

- retinopathy associated with smoking
- neuropathy associated with smoking
- nephropathy associated with smoking

None of the participants:

- had heard of atherosclerosis
- were aware that smoking has been shown to have direct links to the onset of Type 2 diabetes (Rimm, Manson & Stampfer, 1993; Rimm, Chan, Stampfer, Colditz & Willett, 1995; Kawakami, Takatsuka, Shimizu & Ishibashi, 1997; Will, Galuska, Ford, Mokdad & Calle, 2001).

By T2 these responses had become more diabetes specific, for example, nephropathy, neuropathy, eye damage and foot disease and the effects were statistically significant ($F(1, 30) = 16.82$, $p<0.0005$) with 38% variation. The means presented in Table 12 have increased suggesting participants were more aware of the health risks associated with smoking and diabetes by the end of the intervention.

Table 12: Means and Standard Deviations of number of associated health risks identified by participants (n=31)

Outcome Measure	T1 Means (SD)	T2 Means (SD)
Health Risks	8.50 (3.67)	10.64 (0.93)

4.3.7 Weight (kg)

There were no significant effects for weight with only 0.24kg of a difference in means reported at T2. Although weight was a secondary measure it was important to monitor it in the event participants did stop smoking. The changes in metabolism smoking cessation can cause could have had a detrimental effect on glycated haemoglobin levels (Sherman, 2005).

4.4 Summary of Primary and Secondary Outcomes

Table 13 provides a summary of the results. With regard to the primary outcomes positive effects were found in HbA1c levels and for the PCDS – internality, treatment, chance, and doctor control subscales. This followed for the SLoC Internality subscale and for CO levels. No significant effects were found for the PCDS – externality, patient control and foreseeability subscales or for the SLoC – externality subscale.

Consequently the secondary outcomes reported significant effects with regard to the readiness components of dislikes, motivation and confidence. This followed for concerns about stopping smoking, and awareness of smoking cessation products, services and associated health risks.

Table 13: Summary of significant and non-significant effects between T1 and T2

Primary Outcomes	Statistically Significant	Non-significant
HbA1c (mmol/mol)	P<0.0005	
Perceived Control of Diabetes Scale:		
Internality	p<0.003	
Treatment	p<0.0005	
Externality		ns
Chance	p<0.003	
Patient Control		ns
Doctor Control	p<0.0005	
Foreseeability		ns
Smoking Locus of Control Scale:		
Internality	p<0.0005	
Externality		ns
Carbon Monoxide (ppm)	p<0.0005	
Secondary Outcomes		
Readiness to stop smoking:		
Likes		ns
Dislikes	p<0.003	
Motivation	p<0.0005	
Confidence	p<0.0005	
Concerns:		
Smoking		ns
Stopping	p<0.008	
Awareness:		
Products	p<0.0005	
Services	p<0.0005	
Health Risks	p<0.0005	
Weight (kg)		ns

Chapter 5 – Discussion of Study Findings

This research question asked 'Does gaining control of smoking behaviours have a positive impact on glycaemic control in patients with Type 2 diabetes?' The aim was to explore the impact of a longitudinal smoking cessation intervention tailored to participants with Type 2 diabetes who regularly smoked cigarettes. The study had two strands of investigation, primary outcomes and secondary outcomes.

Primary outcome measures used were HbA1c levels (mmol/mol), the Perceived Control of Diabetes Scale (PCDS) (Bradley, 1993), the Smoking Locus of Control Scale (SLoCS) (Georgiou & Bradley, 1992) and CO levels (ppm).

A Minimum Data Set (MDS, Appendix D, pg. 179) was utilized to record secondary outcomes including smoking related information such as; readiness to stop smoking (likes, dislikes, motivation & confidence), concerns about smoking and stopping, awareness of smoking cessation products and services (Attar-Zadeh, 2013) and knowledge of health risks associated with smoking and diabetes. Weight was monitored as a precaution.

The Diabetes and Smoking Cessation Education Programme facilitated the study and provided the educational intervention using motivational

interviewing (Miller & Rollnick, 2001) and behaviour change techniques (Michie, *et al*., 2011a, 2011b) to encourage participants to discuss their smoking behaviours and glycaemic control. This less confrontational method was preferred in anticipation it would encourage participants, rather than healthcare professionals, to give voice to the argument for change.

The study found positive changes for some of the measures between T1 and T2 although none of the participants stopped smoking. Few studies have evaluated smoking cessation interventions for people with diabetes (SLR, pg. 222), nonetheless the limited research available suggests that smokers with diabetes may be less successful in quitting than smokers without diabetes (Tonstad, 2009; Sherman, 2005; Solberg, Desai, O'Connor, Bishop & Devlin, 2004). One possible explanation for the lower quit rates among this group is that stopping smoking is associated with weight gain and may be of concern to people who have diabetes and may already be overweight. It is important therefore that this group is provided with intensive emotional and psychological support in addition to practical diabetes and smoking cessation education, to optimize successful smoking cessation (Tonstad, 2009; American Diabetes Association, 2003).

The following section discusses the main findings and follows the order the outcomes were presented in Chapters 3 and 4.

5.1 Primary Outcomes

5.1.1 Glycated Haemoglobin (HbA1c, mmol/mol)

The recommended glycated haemoglobin level is between 48-53mmol/mol. The significant reduction ($p<0.0005$) in participant glycated haemoglobin to nearer these levels is encouraging. Elevated blood sugar is known to contribute to long-term complications such as coronary heart disease, cardiovascular disease, nephropathy, and neuropathy and in some cases, amputation of the lower extremities. Maintaining glycated haemoglobin within the recommended levels can reduce the risk of developing these complications.

There is increased stiffness of the large central arteries in people with Type 2 diabetes and obesity is a risk factor. Obesity is thought to account for much of the association between insulin resistance and arterial stiffness. Barinas-Mitchell *et al.* (2006) demonstrated that a 7.8% weight loss in participants with Type 2 diabetes resulted in improvements in HbA1c. There was also a significant improvement in aortic pulse wave velocity, which is an indicator of arterial stiffness, at completion of weight loss intervention, ($P < 0.05$). This reduction in levels may be linked to changes in participant perceptions of their control of diabetes.

5.1.2 Perceived Control of Diabetes

The study aimed to investigate patient levels of control and encourage a shift towards an internal locus of control through education. The Perceived Control of Diabetes Scale (Appendix E, pg 182) (Bradley, 1993) helped this investigation and proved useful for determining existing levels of control and the degree to which these levels had changed. It was also useful for understanding individual differences between participants and their preferences for treatments.

This study found statistically significant effects in a positive direction on the Internality ($p<0.003$), Treatment ($p<0.0005$), Chance ($p<0.003$) and Doctor Control ($p<0.0005$) subscales. This change resulted in participants placing more emphasis on their own role in their self-management of diabetes, for example diet and exercise and regular blood glucose monitoring and less emphasis on the role of the healthcare profession, the treatment available and sheer luck. There were no significant effects on the Externality, Patient Control and Foreseeability subscales.

The results appear contradictory in that there may be an expectation that a shift toward an internal locus of control would positively associate with patient control and negatively associate with doctor control, which is not the outcome. The shift toward an internal locus of control suggests that participants are more aware that they could influence their outcomes and perhaps reduce their risk of developing long-term complications. The shift toward attributing

treatment as the cause of having good diabetes control is contradictory to an internal locus of control yet shows that in some cases, participants are aware that outcomes may not be due to external control.

There was a positive increase in the means for the externality, patient control and foreseeability subscales. This is a positive outcome as the literature suggests that individuals demonstrating an internal locus of control are more likely to adhere to treatment and are also more likely to be motivated to self-manage their diabetes effectively.

This is a positive outcome for diabetes care in Forth Valley and while there is still further work to be done and more improvements to be made, the implications of participants taking more control and ownership of their health, are encouraging.

This shift in perceived control of diabetes may be due to the Diabetes and Smoking Cessation Education Programme and its aim to raise participant awareness of their condition. It could also be attributed to the hypothetical scenarios that are aimed at making a situation feel more relevant to the wider population than the participant themselves. The scenarios also encourage participants to think more in-depth about particular situations and this may be the first time that the individual has given these situations any thought at all. For example, an individual who is not having problems with their feet and has

not had in the past may not think about the risks that poor blood glucose control, more specifically high blood glucose levels, can pose to their feet.

Diabetes care currently costs the NHS in Scotland, on average, £1 billion per year to treat which equates to 10% of the total NHS budget (Diabetes in Scotland, 2014; Scottish Executive, 2010). Much of this cost is spent on treating the long-term complications that can arise from poor glycaemic control. An intervention or education programme that begins to address these issues, encourages patients to take ownership of their own health and is also cost effective, should be explored further.

5.1.3Smoking Locus of Control

The SLoCS was investigating where participants believed the responsibility lay for their smoking behaviour. There was a statistically significant change between T1 and T2 on the internality subscale ($p<0.0005$) suggesting that participants placed more emphasis on their own role in stopping smoking and less emphasis on the input from external factors such as family, friends and the healthcare professionals. This is an encouraging finding that suggests participants became more aware that their smoking and future cessation was within their own control and merits further exploration to inform smoking cessation education and techniques.

5.1.4 Carbon Monoxide Levels (CO)

Carbon monoxide testing is mandatory in all smoking cessation services in Forth Valley. It is not a definitive measure of cessation, only an indicator of a quit attempt or a reduction in cigarette consumption. CO monitoring can be a motivational tool when the breath test results are decreasing yet have an adverse effect if the opposite occurs. This study used it as a motivator and an introduction to tobacco use and cigarette consumption. In addition it was a useful tool for the DSCEP to educate participants as to what the results meant in terms of PPM and %'s and in real terms with regard to their diabetes and general health. Although none of the participants stopped smoking it was encouraging to find a statistically significant decrease in CO levels ($p<0.0005$) post-intervention.

5.2 Secondary outcomes

5.2.1 Tobacco Use

Tobacco use data were collected as the level of addiction often becomes apparent during these types of discussions. For some the addiction may be physiological or pharmacological but for the majority of smokers the addiction tends to be psychological. Just under half of the participants in this study (45%) demonstrated high levels of nicotine or pharmacological dependence by reporting that they smoked their first cigarette within five minutes of waking. Contradictory to this, participants did not tend to waken during the night for a cigarette (91%) or smoke more during the morning (69%). A greater number

of cigarettes smoked in the morning is an indication of a higher level of nicotine dependency (Heatherton, Kozlowski, Frecker & Fragerstrom, 1991). This question may have been slightly ambiguous as the morning tends to be a shorter time frame than the afternoon and evening and the question may have been misleading.

Although participants smoked less in the morning, 69% reported that the hardest cigarette to give up would be the first one in the morning. This may be due to the fact that their nicotine levels would have depleted overnight. By morning participants would be in a state of nicotine withdrawal, which for some can be a very unpleasant feeling.

Thirty-six percent of participants advised that it would be hard to abstain from smoking for a whole day while 58% reported they would have to smoke if confined to bed, for example, with illness. Interestingly, 81% advised that they would not have to smoke if they were in a restricted area, for example, a long haul flight or hospital. This suggests that if the element of choice is removed, people can abstain from smoking for long periods.

Cigarettes are highly engineered products designed to ensure that nicotine reaches smokers' brains seconds after they inhale the smoke. Smokers can rapidly become dependent on the "hit" they receive from nicotine, which can

make it hard for many to stop. Most people smoke to satisfy their habit or to alleviate symptoms of withdrawal and craving (ASH Scotland, 2014; Foulds & Ghodse, 1995).

As well as this physiological dependence, smoking cigarettes can be reinforced and sustained by a range of factors, including sensory, behavioural and social conditioning. In his book A Theory of Addiction, West (2006) notes that many people who smoke are prompted to do so by cues such as seeing others smoke. Others have strong smoking associations with an alcoholic drink, ending a meal or talking on the telephone perhaps. Cigarettes can also be used as a prompt to take a break, help people to relax or as a reward in line with positive reinforcement. These stimuli continue to be present when people decide to stop and can often contribute to relapse. To stop smoking and to maintain a quit attempt, new behaviours and associations have to be established, which can take time and several attempts (West, 2006).

In addition to the issues of behavioural associations, when smokers try to stop they can also be affected by unpleasant withdrawal symptoms such as poor concentration, irritability, anxiety and depression. Dependence on nicotine is classified as an addiction as these strong withdrawal symptoms can make stopping extremely difficult.

Stopping smoking can be a difficult process because people are required to simultaneously overcome their addiction to nicotine, break a long established habit and cope with physical withdrawal symptoms. It is this combination of challenges that is thought to account for why only 3% of smokers who stop using willpower alone, stay stopped. When smokers are given ongoing motivational and behavioural support, treatment and follow up, the percentage who successfully maintain a quit attempt for twelve months without relapsing increases to 20% (West, McNeil & Raw, 2000).

This may be one of the contributing factors as to why none of the participants stopped smoking. The pre- and post-interventions were twelve months apart and therefore not ongoing. Had the motivational and behavioural support been offered on a more regular basis, participants may have felt more motivated and confident to stop smoking. The long break in between may also have impacted negatively on the participants readiness to stop smoking.

5.2.2 Readiness to Stop Smoking

5.2.2 Likes and Dislikes of Smoking

Readiness to change behaviour, as originally defined by Rollnick, Butler and Stott (1997), incorporates the concepts of likes and dislikes of smoking and motivation and confidence and confidence to stop smoking.

A few of the participants liked the fact smoking relaxed them and gave them time to themselves. In all cases participants disliked the cost, the smell and the negative impact on health associated with smoking, and in that precise order. It was interesting to find that there were no statistically significant changes with regard to what participants liked about their smoking yet dislikes changed significantly ($p<0.003$) in a positive direction. Most participants at this point had a dislike of everything associated with smoking. This contradiction may have resulted from a misunderstanding of the question where participants thought they were being asked what they liked previously about smoking and not what they liked presently. They may also have felt obligated to say what they thought the researcher wanted to hear rather than what they actually felt. Another consideration is that although levels of motivation and confidence to stop smoking increased, perhaps this did not transfer to vocalizing feelings.

5.2.2b Motivation and Confidence to Stop Smoking

Carrying on the readiness to change concept (Rollnick, Butler and Stott, 1997), examples of motivation and confidence illustrate these concepts and their relationship to readiness. Firstly, a male who desperately wants to stop smoking but is fearful of the feelings of withdrawal and mood swings and secondly, an international sports person who feels they could stop at any time but chooses not to stop because smoking is part of their social life. These individuals, respectively, are described as being high in motivation but low in

confidence and high in confidence but low in motivation. Although motivation and confidence are distinct concepts they are clearly interconnected.

One way of beginning to understand a person's readiness to change their health behaviour in greater depth is by exploring their expectations of the costs and benefits of change (motivation) and their ability to master the demands of abstinence (confidence).

These two concepts have a number of reference points in psychological theory, for example, the Stages of Change Model (Prochaska & DiClemente, 1984). Research on this model has revealed some consistent shifts in these expectations as people move through the stages (Rollnick, Morgan & Heather, 1996; Dixon, 2008). The guiding assumption is that for a person to move into the preparation stage ('I'm ready to try') they must believe that change is worthwhile (motivation) and that they can succeed (confidence). West (2004) questions the simplicity of this model in its application to smoking cessation. He argues that individuals do not make stable plans and also that the model ignores the fact addictive behaviour is often automated.

Even so this study demonstrates a significant change in a positive direction for levels of confidence and motivation which may be as a result of the

intervention instigating a deeper understanding of the implications of continuing to smoke.

The present study explored motivation and confidence by using motivational interviewing techniques. The aim was to build participant motivation and confidence to stop smoking and to maintain their glycated haemoglobin nearer to the recommended levels of 48-53mmol/mol. This was done by encouraging participants to identify arguments for change (motivation) and practical and achievable steps for stopping smoking (confidence). For example, the DSCEP asked participants if they knew the health risks associated with smoking with diabetes and proceeded to fill in any gaps in knowledge. They were then asked to identify arguments for change that could potentially reduce their risk of developing long-term complications and to suggest achievable goals that would help them to reduce cigarette consumption or stop smoking completely.

In fact, Tuckett, Boulton and Olsen (1985), have shown that consultations are more productive when the doctor is seen as the expert information giver and the patient is seen as the expert in his or her own beliefs and daily life. Similarly, Stott (1990), in a study of working class women, reports that patients are more inclined to be receptive to information sharing than being told what to do.

More recently, a systematic review has reported that adopting shared decision-making protocols has been slow with attitudinal barriers hindering the process and patients are finding it hard to speak up. The authors suggest that patients need to be prepared for shared decision making and it may not come naturally (Joseph-Williams, Edward & Elwyn, 2014)

Nevertheless, motivational interviewing and patient-centred consulting can be problematic. For example, healthcare professionals can have a limited motivational repertoire and sense of low self-efficacy when it comes to influencing patients' health behaviour change. They can also struggle with lack of motivation from patients and pressures of time and resources (Rubak, Sandbæk, Lauritzen & Christensen, 2005). The failing is therefore not directly related to the technique itself but rather in its implementation.

This study can identify with many of these challenges. Intervention time was limited with each patient as it occurred during their annual review. The period between study introduction and participation was short, in some cases less than one hour. This may not have allowed participants sufficient time to internalize all of the information given to them with which to make a fully informed decision to participate. Equally the motivational interviewing skills of the researcher may not have been of a standard sufficient enough to instigate smoking cessation among the participants.

A report by the Picker Institute Europe (2006) shows that despite a strong commitment to patient-centred care, people living with long-term conditions in the UK were less positive about their care than in other westernized countries.

British people with long-term conditions were the least likely to:

- say that they had received opportunistic advice from their doctor on disease prevention and lifestyle modification, for example, weight, diet and exercise
- be involved in treatment decisions
- have participated in a treatment review
- have been given information about the side-effects of their medication and
- have been informed about possible side-effects.

The survey also showed that within the UK:

- Fewer than half of people were involved in shared decision-making, compared with around two-thirds of people in New Zealand
- Only 54% of people with chronic conditions were given dietary advice

Fewer than 1 in 5 people with chronic conditions had been given a plan for managing their self-care at home. This fell to 1 in 10 for people diagnosed with diabetes.

That said, statistically significant differences in levels of motivation (p<0-0005) and confidence (p<0.0005) were found between T1 and T2. With regard to motivation, this may be due to the fact that the DSCEP informed participants of the risks they posed to their health. According to some, it was the first time a health professional had discussed smoking and diabetes in detail and not merely as additional information given at annual review. Perhaps the motivational interviewing technique was the catalyst that motivated participants to adopt positive health behaviours.

Being part of a programme designed to inform and support health behaviour change with participants central to the discussion and decision making process, may have contributed to increased levels of confidence been a novel experience for some of them that allowed them to discuss their concerns in a safe environment.

5.2.3 Concerns about Smoking and Stopping Smoking

The Smoking Cessation Guidelines (NHS Health Scotland & Ash Scotland, 2010), set out the recommendations for those involved in smoking cessation in Scotland and includes an evidence base for brief advice. Brief advice to stop smoking involves opportunistic advice to smokers to stop and the recommendation to use treatment, for example, the NHS Scotland Smoking Cessation Service, to help them to do so. This advice should normally take less than three minutes.

The evidence suggests that brief advice given by a GP, and lasting less than three minutes, results in approximately 5% of all smokers stopping for at least six months (ASH Scotland, 2010). This is independent of age, gender and whether the person has any smoking-related diseases.

In Forth Valley, this is the most common form of smoking cessation intervention as it is quick to administer, reaches a larger number of people and is cost effective. In fact, most health care professionals are now trained in giving brief advice but it is not an effective intervention for supporting a quit attempt. The guidelines emphasize that brief advice is most effective in triggering a quit attempt, but that support to actually aid a quit attempt is best delivered by trained, specialist staff over a period of time (NHS Health Scotland & ASH Scotland, 2010).

The NHS Forth Valley smoking cessation service offers two main services; evening drop-in clinics which have a rolling group format and Maudsley groups, which are closed and are held weekly for approximately one hour. Maudsley groups are based on the service provided at the London Maudsley Hospital and training is provided locally by Professor Hajek, a clinical psychologist and founder of the Maudsley programme (Hajek, 1994). The programme is very prescriptive with weekly topics predefined as follows:

Week 1	Introductory Session – housekeeping, introductions, group agreement, confidentiality, benefits of group work, set quit date
Week 2	Preparation for Quitting – CO monitoring, feelings about quitting, share previous quit experiences,
Week 3	Quit Day – share thoughts and feelings about reaching quit day, share coping strategies
Week 4	Responding to group needs, monitoring programme – discuss issues and challenges
Week 5	Responding to group needs, monitoring progress – discuss issues and challenges
Week 6	Preventing relapse, closure – draw on learning from previous weeks, define lapse and relapse and offer additional support if required

The evening drop-in clinics offer a rolling group service and are not prescriptive. They cover most, if not all, of the topics discussed in the Maudsley sessions as interventions progress and needs arise.

With personal experience of delivery Maudsley programmes on numerous occasions in Forth Valley there is very little time devoted to smoking in relation to specific health conditions. The format is very much on the process of stopping smoking and focuses on smoking history and patterns, withdrawal

symptoms and coping strategies and preventing relapse. Questions are answered as fully as possible and additional information provided where appropriate but constraints on resources leave very little opportunity for one-to-one sessions where an individual can raise concerns regarding smoking in relation to their specific health conditions such as diabetes, coronary heart disease or COPD.

The DSCEP aimed to address this by incorporating questions that asked participants what health-related concerns they had about remaining a smoker and about stopping smoking. At T1 concerns regarding remaining a smoker included: cost and health risks such as cancer and heart disease. By T2 the concerns had become more diabetes-specific and included amputation, erratic blood glucose levels, neuropathy and nephropathy. This change was not statistically significant.

Although none of the participants stopped smoking there was a statistically significant positive change in concerns about stopping smoking ($p<0.008$) at T2. Participants were concerned with mood swings; in particular, low mood and weight gain (discussed in section 5.2.3, pg. 133). Both of these can be quite common for anyone stopping smoking but for an individual with diabetes, they can be particularly problematic.

Depression affects approximately 20% of people with diabetes and is twice as high among this population as it is among the general population. It affects more women than men in both the general and diabetic populations but men with diabetes are more at risk of developing depression than men in general (NICE, 2009; Lin, Katon & von Korffe *et al*, 2004; Jacobson, Samson, Weinger & Ryan, 2002; Anderson, Freedland, Clouse & Lustman, 2001). The nature of depression in diabetes is complex and adverse life events, the severity of the condition and genetic and personality factors are all likely contributors to its occurrence. Whether depression is more common in diabetes than in other long-term conditions is far less supported in the literature.

The DSCEP discussed low mood and weight gain at length and strongly advised participants to speak to their doctor if they noticed any negative effects during a quit attempt. Since levels of motivation and confidence to stop smoking both resulted in statistically significant increases therefore mood swings and low mood were not an issue for the participants of this study.

5.2.4 Awareness of Smoking Cessation Products and Services

Participants were asked if they had previously had discussions with healthcare professionals with regard to smoking with diabetes. Fifty-nine percent (59%) of participants said they had not. This claim was challenged by senior staff and consultants, who questioned if participants were in denial. It is possible that patients are overwhelmed with information during an annual

review and information on stopping smoking gets lost. It is also possible that patients have selective memory and retain the information they want to.

Initially there was limited awareness of the range of products available to support a quit attempt. Ninety-four percent (94%) of participants were aware of NRT transdermal patches while only 35% had heard of NRT gum. None of the participants were aware of the NRT nasal spray or of Zyban, an anti-depressant tablet used as a smoking cessation aid. The DSCEP addressed this by providing information and literature on the range of products available including patches, gum, tablets, oral and nasal sprays, microtabs and inhalators and their instructions for use.

The numbers were lower for awareness of smoking cessation services. Only 31% were aware of the GP service. Not all GP surgeries in Forth Valley offer a specialist smoking cessation service preferring to refer patients to their local evening drop-in clinic for specialist advice or directly to the Pharmacy service. This practice continues today. Twenty-six percent (26%) of participants advised that they had no knowledge of services at all.

This study found statistically significant differences between T1 and T2 for awareness of smoking cessation products ($p<0.0005$) and services ($p<0.0005$) suggesting participants knew what could help them to stop smoking and where to go for specialist advice out-with the DSCEP and beyond this study.

As was mentioned earlier this component was not a test of memory *per se*. It was included simply to determine whether participants were aware of the range of help available and an opportunity to discuss developments in pharmacotherapy, such as the tablet-treatment Champix, e-cigarettes/ vaporizers and expansion of service delivery.

E-cigarettes and vaporizers were released to market after this study finished and were therefore not relevant to discussions. However, There has been a recent increase in their usage in the UK (3 million sold in 2012, NHS News [accessed August 2014]) and ASH Scotland caution their use until regulation is granted in January 2016 (ASH Scotland, 2014).

5.2.5 Associated Health risks

This move to e-cigarettes and vapourisers highlights a growing awareness of risk to health that smoking poses, in general. In this case there was also a good degree of awareness.

In light of this evidence, atherosclerosis, nephropathy, neuropathy and diabetic foot from circulatory problems were described and their causes and implications for diabetes were discussed at length throughout the DSCEP.

It is important that people with diabetes are given sufficient information to help them self-manage their condition and it is even more important that this

information is communicated in a safe environment and in a way that helps patients feel part of the discussion and decision making process.

Motivational interviewing was used to elicit these responses from participants and to encourage more in-depth discussions. These discussions were designed to increase the importance of health behaviour change, from the participants' perspective. This was accomplished by asking specific types of questions, for example, open and closed questions, along with selective reflections that directed participants toward the discrepancy between their negative health behaviour and broader personal values. Motivational interviewing is intentionally directive. In line with the Motivational Interviewing Network for Trainers Manual (MINT, 2008) and evidence from systematic reviews of the efficacy of MI for drugs, alcohol, weight gain, diet and exercise and smoking cessation (Lai, Qin & Tang, 2008; Rubak, Sandbæk, Lauritzen & Christensen, 2005; Burke, Arkowitz & Menchola, 2003; Knight, Dickens, McGowan & Bundy, 2006), the researcher was careful not to explicitly advocate for change.

There were also significant effects in awareness of health risks ($p<0.0005$) with the educational input from the DSCEP. Over time this knowledge became more diabetes specific. Participants became more aware of the risks to health that their smoking behaviour poses and in terms of an education programme, these findings suggest that the intervention may have been effective.

5.2.6 Weight (kg)

In this instance there were no significant changes in weight loss but there was a reduction in the weight means, suggesting a small degree of weight loss. Weight gain can contribute to diabetes complications and should be monitored closely.

Weight gain is associated with smoking cessation and tends to concentrate in the central subcutaneous regions (Aubin, Farley, Lycett, Lahmek & Aveyard, 2012; Fillizof, Fernandez-Pinilla & Fernandez-Cruz, 2004). Increased abdominal fat is a risk factor for coronary heart disease and Galal, van Domburg, Feringa and Shouten (2007) reported that body mass index is an independent predictor of long-term mortality.

Nicotine is known as an appetite suppressant and smoking is often used, among other things, as a mechanism to control weight. Haire-Joshu and Thomas (2005) suggest that people with diabetes believe that excessive post cessation weight gain will interfere with their self-management and that this may contribute to fears about stopping smoking.

The participants in this study voiced their concerns regarding weight gain stating that they thought stopping smoking may adversely affect their blood glucose levels which they wanted to avoid. With none of them stopping smoking, weight gain was not an issue for this study.

5.3 Study limitations and Methodological Weaknesses

The group under investigation was not representative of the general public and is the main reason the study was exploratory in nature. Despite this the study had a great deal of support in Forth Valley from the diabetes care department, the smoking cessation department, the health promotion department, the Forth Valley Tobacco Action Group and also from health psychology colleagues at Queen Margaret University and Stirling University. In addition, the project won the first ever Cardiovascular and Diabetes Award from Servier Laboratories in collaboration with the Royal College of Nursing.

Despite this support, the study was beset with challenges from the outset. The process to gain ethical approval should take approximately two – three months to complete. It was sixteen months before approval was granted. The delays were partly due to naivety of the researcher and to confusion within the NHS Forth Valley Research and Development Department (R&D) relating to the research objectives and the sample available. The researcher misunderstood that the NHS ethics application form should also have been sent to R&D for both process to run concurrently. As this did not happen it caused more delays.

The study was due to run in Falkirk Royal Infirmary (FRI) and Stirling Royal Infirmary (SRI) on Friday and Wednesday mornings respectively which should have given access to a sufficient sample. Because of the delays SRI could not

host the study as the dedicated room had been booked for other purposes. This meant the only timeslot was Friday mornings in FRI greatly reducing access to patients.

During initial meetings with diabetes care and smoking cessation mentors the researcher was asked to focus the research on participants with Type 2 diabetes who smoked cigarettes. It was explained the intervention could have a negative impact on patients with Type 1 diabetes or using insulin. Initially this did not appear problematic. When the study began it became evident that most patients with Type 2 diabetes are managed in primary care and not secondary care, again narrowing the sample. As a result participants became difficult to find.

Twenty-nine participants were required for statistical power. Due to potential attrition, forty-five participants were sought. Participant recruitment did not prove problematic and thirty-one participants took part at baseline. All of them agreed to return to FRI for 3-month follow-up. None of them did despite agreeing to an appointment. To collect 3-month data, the researcher posted questionnaires to the participants with a covering letter of explanation and a stamped addressed envelope. None of the participants returned their questionnaires.

It was agreed with diabetes care and QMU that 3-month follow-up would be removed from the study and 6-month and 12-month follow-up data would be collected. It was anticipated this would be less of an issue as some of the participants were due for diabetes review at 6-months and all would return for annual review at 12-months. As suggested seventeen participants returned at 6-month and twenty-nine returned at 12-month. One participant died soon after entering the study. Further guidance from statisticians at QMU advised to remove the 6-month follow-up data and to concentrate on baseline and 12-month follow-up data.

At the beginning of the study participants were slow to complete the questionnaires and it was difficult to have a discussion while they were concentrating. The sessions became lengthy which left less time to recruit new participants. In order to leave time to build rapport and not to rush the intervention the researcher felt it prudent to read the questions aloud to participants and populate the forms with their responses during the intervention. In doing so the session was more effective and allowed time for interaction and discussion.

Although this format was followed for all participants, it is contradictory to the advice given by Bradley (1993), who advises that participants must complete the questionnaires by themselves and in the time it naturally takes them. It is acknowledged that, while every effort was made to ensure that each

participant received the same intervention, the researcher may have introduced bias by reading and completing the questions for the participants and thus may have given variations in explanations.

On reflection the intervention was perhaps too long, particularly after a diabetes review which in itself could be lengthy and tiring. It was evident that some participants were becoming disinterested and may have given answers for the sake of saying something as opposed to what they really felt. There is also the possibility that some responded with what they thought the researcher wanted to hear in case it negatively affected their diabetes care. The Perceived Control of Diabetes Scale perhaps could have been abridged and would not have taken up so much of the DSCEP leaving more time for discussions.

Other issues arose depending on the number of consultants holding clinics at the same time. Some Friday mornings there would be one consultant clinic and other Friday mornings three consultant clinics. With one consultant, the research ran smoothly with sufficient time for the intervention. With three consultants it could, and did, become chaotic. The waiting room became very busy and patients who had been approached with the information letter were being called in to consultations before they had time to consent. Others who were returning at 12-month follow-up would present to the research room and half-way through the intervention, would be called by the consultant for their diabetes review. This happened mostly when clinics were running late and the

researcher attempted to maximize time. Such a disjointed approach was not conducive to an effective study but as the DSCEP did not want to encroach on diabetes care or consultant time, the researcher did what they could to keep participants motivated. This was not a weekly issue but did happen quite often and had not been anticipated.

There was no control group included in this study. Although many of the effects were statistically significant, without a control group it is difficult to attribute the behaviour change to the intervention and is possible the changes may have occurred naturally with time.

It was decided not to include a control group for the ethical reasons discussed earlier and also because of time and resources. The research received funding from Servier Laboratories and the Forth Valley Tobacco Action Group but the funding only supported one researcher. Other doctoral competencies limited the researcher's availability to Friday and Wednesday mornings which was further limited to Friday mornings when SRI could not accommodate the study. Under these circumstances to try to accommodate a control group would not have been practical and is why the research became an exploratory study.

Although the research aimed to motivate participants to stop smoking and anticipated gaining control of smoking behaviours would have a positive impact on glycaemic control in patients with Type 2 diabetes, these goals

were not attained in their entirety. None of the participants stopped smoking although some reported cutting down. The carbon monoxide readings supported this to some extent but since carbon monoxide depletes from the body as soon as the last cigarette has been smoked, these readings cannot be taken as definitive proof of a reduction in cigarette consumption. A fundamental flaw of the study was not to capture cigarette consumption at T2. This was a complete oversight on the part of the researcher with no rationale.

The DSCEP invited participants to return to FRI any Friday morning should they wish smoking cessation support. It was recognized that FRI is not always easy to get to and parking is an issue. With this in mind the DSCEP informed participants of smoking cessation clinics and groups running in their own area. Disappointingly, none of the participants returned for smoking cessation support out with their diabetes review or attended a clinic nearer home. The reasons for this are not clear.

When patients arrived for their annual diabetes review they would have no prior knowledge that a study was running in the department. Whilst the researcher did not knowingly coerce anyone into taking part, it is possible that some patients may have felt obliged to take part, worried that their diabetes care would be compromised if they did not. It is not known what advice or information the consultants gave patients regarding the research and taking part or if any other healthcare professionals advised patients to take part. Stopping smoking may not have been on the patient's agenda and the

timescale between being invited to participate and actual participation may have been too brief for some.

It is fair to say the research was too ambitious for one person, particularly a student with limited research experience. The research and DSCEP was well intentioned and had many supporters. On reflection, there were too many components and at times it felt fragmented. The statistical analysis, repeated measures ANOVA, could have been supported by additional research methods to provide a broader understanding of the findings. For example, the non-parametric Friedman Test although this is a less sensitive measure, factor analysis could perhaps have identified patterns of correlations between variables (was SLoC correlated to levels of motivation and confidence?). Equally linear regression may have helped uncover a relationship between variables not evident from ANOVA alone.

The preceding pages offer the building blocks of an important and valuable research programme that with the appropriate levels of funding and expert guidance will help people with Type 2 diabetes in their attempt to stop smoking. The impact will be a reduction in risk of developing long-term complications and premature morbidity and mortality. It is cost-effective and will reduce the burden on NHS resources both locally and nationally.

Chapter 6 - Conclusions

Although the study proved challenging at times there were some interesting, if not contradictory statistically significant outcomes. For example, significant effects were found for the SLoCS internality but not externality subscales, dislikes of smoking but not likes of smoking, concerned about stopping smoking yet not concerned with smoking and PCDS internality but not externality subscales. An in-depth exploration of these particular outcomes was beyond the scope of this study.

These findings suggest a positive outcome for healthcare. The literature reports that people who are more inclined to take control of their own health behaviour are more likely to adhere to their medicine and engage with the healthcare profession. In terms of diabetes care, this can only be a positive step in reducing the potential risk of patients developing long-term complications which in turn should reduce the burden on overstretched resources. This merits further investigation.

In response to the research question “Does gaining control of smoking behaviours have a positive impact on glycaemic control in patients with Type 2 diabetes?” the findings suggest it does.

6.1 Why the DSCEP is a good example of shared practice

Many research papers call for intensive smoking cessation support for people with diabetes. This Diabetes and Smoking Cessation Education Programme responded to this call without encroaching on consultant or specialist nurse time, allowing the health professionals to focus on delivering diabetes care.

6.2 Recommendations

In light of the current findings, the following recommendations are suggested:

- The DSCEP becomes an integral part of routine diabetes care in primary and secondary care
- The DSCEP be developed to include patients with Type 1 diabetes
- A randomized controlled trial is developed
- Explore the impact and efficacy of e-cigarettes and vaporizers

6.3 Accountability

The study was granted ethical approval from:

- NHS Lothian Research Ethics Committee
- NHS Forth Valley Research and Development Department
- Dr Norman Peden Senior Diabetes Consultant NHS Forth Valley Diabetes Care Department
- Queen Margaret University Ethics Committee

and supported by:

- Sister June Currie Senior Diabetes Specialist Nurse, NHS Forth Valley
- Sister Gillian Bruce Specialist Lead Nurse in Smoking Cessation, NHS Forth Valley
- Dr. Vivien Swanson CPsychol., MSc Health Psychology Course Director, University of Stirling

and was supervised by:

- Dr. Michèle Hipwell CPsychol. Professional Doctorate in Health Psychology Deputy Course Director, Queen Margaret University, Edinburgh
- Dr. Vivienne Chisholm CPsychol. Senior Lecturer, Queen Margaret University

6.4 Resources

The project secured funding via the first ever Servier RCN Diabetes/CHD Award for 2006. This enabled the project to employ a trainee health psychologist for 3 hours per week for the first year and to purchase a carbon monoxide monitor. NHS Forth Valley Health Promotion awarded funding to continue the project for a further 12 months on the same basis. The project is currently seeking additional funding.

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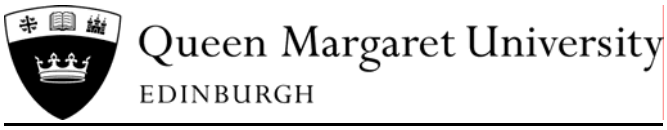
APPENDICES

APPENDIX A



Participant Information Letter

Protocol version: 2

REC Reference Number: 07/S1102/50

Study Title: Does gaining control of smoking behaviours have a positive impact on glycaemic control in patients with Type 2 diabetes?

PART 1

The research is being conducted as part of the Professional Doctorate in Health Psychology with Queen Margaret University (QMU) and Forth Valley Diabetes Care. The study aims to determine whether gaining control of smoking behaviours i.e. cutting down cigarette consumption or stopping smoking completely, will have a positive impact on blood sugar levels in patients with Type 2 diabetes. The study aims to recruit 45 participants in Forth Valley and you are being invited to participate because you have been identified from your case notes as a patient with Type 2 diabetes who smokes cigarettes.

The researcher will describe the study and go through this information sheet, which will then be given to you. You will be asked to sign a consent form to show you have agreed to take part. Your participation is entirely voluntary and you are free to withdraw at any time, without giving a reason. Please be assured that this will not affect the level of diabetes care you receive.

What will my involvement be?

The study will be conducted over a 12 month period. You will meet with the researcher for 30 minutes at an appointed time, once every 3 months (4 times in total). At these meetings you will be required to:

- give demographic information (age, gender, ethnicity, education level)
- discuss your smoking history and smoking patterns
- complete perceived control of diabetes questionnaire
- complete smoking locus of control questionnaire
- participate in carbon monoxide testing
- participate in HbA1c testing
- be weighed

What happens to the information gathered on me?

All information gathered will be stored in a locked cabinet in Diabetes Care and will only be viewed by the researcher and the researchers' Director of Studies at QMU. The data will be entered into a secure database at Queen Margaret University and analyzed using repeated measures ANOVA. This is a research method that allows researchers to track changes in participants' behaviour over time. The findings will be written up as a dissertation and submitted to QMU's examination board. All participants will receive a letter advising them of the results of the study.

Confidentiality

Your confidentiality will be safeguarded in accordance with the Data Protection Act, 1988. All information gathered will be held in the strictest confidence and viewed only by those directly involved with the study. You will be allocated with an identification number that will be recorded on all of the paperwork associated with your participation. This will ensure that you cannot be identified by name or address, guaranteeing anonymity. The study follows British Psychological Society Ethical Guidelines and has been reviewed and given a favourable opinion by Lothian Local Research Ethics Committee 02. All findings included in reports will be written anonymously.

How can I benefit from taking part?

The study is not guaranteed to help you but the information gathered from the study will help develop an education programme aimed at helping patients to manage their diabetes more effectively and to stop smoking. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

Withdrawal from the study

Participation in the study is entirely voluntary and you are free to withdraw at any time without giving a reason. Withdrawal from the study will not affect your level of diabetes care. Data given by you, up until your time of withdrawal, will be included in the study.

Who do I complain to if I am not happy with the study?

If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions (01324 624000 ext 6094). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from Falkirk District Royal Infirmary, Diabetes Care Department. Additionally, Queen Margaret University is indemnifying participants in this study for any harm arising to them from the management, design and conduct of the research. Please contact Queen Margaret University on 0131-474-0000 if you feel you have grounds to complain under these arrangements.

Involvement of your GP

If you participate in the study, a letter will be sent to your GP advising of this. Stopping smoking can affect your blood sugar levels and may lead to weight gain therefore your GP may wish to monitor you more closely.

Further information and contact details

Please direct all enquiries to Margaret-Anne MacMillan, Trainee Chartered Health Psychologist, 01324 624000 ext 6094.

Appendix B

Queen Margaret University
EDINBURGH

Participant Consent Form
Protocol version: 2

REC Reference Number: 07/S1102/50

Study Title: Does gaining control of smoking behaviours have a positive impact on glycaemic control in patients with Type 2 diabetes?

Researcher: Margaret-Anne MacMillan

Participant ID: **DSCEP/F……**

Please read the Participant Information Letter and then complete the following (initial the boxes and sign and date the Participant Consent Form at the bottom).

1.I confirm that I have read and understand the information sheet dated 15.3.08 (version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2.I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3.I understand that data collected during the study, may be looked at by individuals directly involved with the study. I give permission for these individuals to have access to my records. ☐

4. I agree to my GP being informed of my participation in the study. ☐

5. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature
_____	_____	_____

APPENDIX C – GP LETTER

Forth Valley NHS Board

Diabetes Care Centre

Falkirk District Royal Infirmary

Majors Loan

Falkirk

www.show.scot.nhs.uk/nhsfv

hpenquiries@fvhb.scot.nhs.uk

Date

Confidential

Our Ref Diabetes and Smoking Cessation Education Programme

Enquiries Margaret-Anne MacMillan

Extension 6094

Tel 01324 616041

Email

Dear Dr.

Patient attending Diabetes and Smoking Cessation Education Programme

I am writing to inform you that your patient …… (DOB) …… has entered the Diabetes and Smoking Cessation Education Programme at Falkirk/Stirling Royal Infirmary. The programme is aimed at patients with diabetes who smoke. The programme is delivered by myself, a trainee Health Psychologist and is supervised by June Currie, Diabetes Specialist Nurse and Gillian Bruce, Smoking Cessation Specialist Nurse. The education programme aims to motivate patients to self-manage their diabetes more effectively and to quit smoking, by raising awareness of the health risks associated with diabetes and smoking. The programme discusses coronary heart disease, ischemic heart disease, atherosclerosis, stroke and circulation and advises on NRT, Zyban and Champix and smoking cessation services available within Forth Valley.

I have discussed with your patient the areas of support that are available and as such they may contact you regarding NRT and other therapies.

As you will be aware, stopping smoking can affect glycaemic control and your patient may need careful monitoring. However, NRT is known to be a safe and effective method of smoking cessation support for patients with diabetes and I would therefore ask that you consider prescribing NRT for your patient should they choose to stop.

Should you have any queries regarding the Diabetes and Smoking Cessation Education Programme please contact Margaret-Anne MacMillan, Trainee Health Psychologist on 01324 616041 ext 6094.

Yours sincerely

Margaret-Anne MacMillan

Trainee Health Psychologist

Queen Margaret University

Appendix D

SCOTTISH SMOKING CESSATION MINIMUM DATA SET

NHS Forth Valley

Participant ID: DSCEP/F

Contact Details:

Title	**Mr Mrs Ms Miss**
First Name	
Surname	
Address	
Postcode	
D.O.B.	
Tel No	
Mob No	

General Practitioner Details:

Name:	
Address	
Town	
Tel No	

Referral by	**Case notes**	☐
	Consultant	☐

Personal Details:

Gender	**Male**	☐
	Female	☐
	Pregnant Y/N	**Y/N**

Diabetes Type	**Type 1**	☐
	Type 2	☐
	Unknown	☐

Education Level	**Secondary**	☐
	College	☐
	University	☐

Ethnic Origin

Employment Status

Biomedical Measures			
Date:	HBA1c	CO	Weight

Information given	**tick**
Participant information form	
Ash factsheet 11 & 23	
NRT, Zyban & Champix info	
SCS signpost leaflet	
How to stop smoking book	

Follow-up arranged	**Yes***	☐
	No	☐

***Date of follow-up**			

Participant ID: DSCEP/F				**Tobacco Use**	
First cigarette on waking?			Average number smoked per day?		
Wake for cigarette during night?	☐ Yes ☐ No		How easy/hard to abstain for a day?		
Smoke more during morning?	☐ Yes ☐ No		Cigarette hardest to give up?		
Smoke if confined to bed?	☐ Yes ☐ No		Difficulty in not smoking in restricted area?	☐ Yes ☐ No	
Other tobacco use?	☐ Pipe ☐ Cigars ☐ Rolls	Age Started Smoking?	Fragerstrom Score	Health over last 12 months?	☐ Good ☐ Fairly good ☐ Not good
No of quit attempts in last year?			Date of last quit attempt?	_ _/ _ _/ _ _	

Readiness to Quit	
What do you like about your smoking?	What do you dislike about your smoking?
On a scale of 1-10, (1=not at all motivated to quit, 10=100% motivated to quit) what number would you give yourself just now?	On a scale of 1-10, (1=not at all confident to quit, 10= 100% confident to quit), what number would you give yourself just now?

Concerns		
What concerns you about remaining a smoker?	What concerns you about stopping smoking?	What concerns you about remaining abstinent?

Awareness	
Have you had previous discussions with health professionals regarding diabetes and smoking? ☐ Yes* ☐ No *please specify	On a scale of 1-10, (1=not at all motivated to quit, 10= 100% motivated to quit), did this previous advice motivate you to quit smoking?
What smoking cessation services are you aware of?	Have you used any of these services? ☐ Yes* ☐ No *please specify
What types of NRT are you aware of?	Have you used any of these treatments? ☐ Yes* ☐ No *please specify
Please list the health risks associated with diabetes and smoking	

Goals	
What are your goals for 3-month follow-up?	What can I do to help you achieve these goals?

Participant ID: DSCEP/F

NHS Forth Valley

6/12-month follow-up			
Contacted for 6/12-month follow-up?	☐ Yes ☐ No	Date follow-up conducted	_ _/ _ _/ _ _
Quit date __/__/__	Smoked since intervention? ☐ Yes ☐ No	CO reading confirms quit? ☐ Yes ☐ No	

Intervention used in quit attempt	NRT/Zyban used?	Where did intervention occur?
☐ DSCEP	☐ NRT	☐ Hospital
☐ Group Support	☐ Zyban	☐ Drop-in Clinic
☐ One to One	☐ Champix	☐ GP Surgery
☐ Pharmacy	☐ Other	☐ Pharmacy

Readiness to Quit	
What do you like about your smoking?	What do you dislike about your smoking?
On a scale of 1-10, (1=not at all motivated to quit, 10=100% motivated to quit) what number would you give yourself just now?	On a scale of 1-10, (1=not at all confident to quit, 10= 100% confident to quit), what number would you give yourself just now?

Concerns		
What concerns you about remaining a smoker?	What concerns you about stopping smoking?	What concerns you about remaining abstinent?

Awareness	
What smoking cessation services are you aware of?	Have you used any of these services? ☐ Yes* ☐ No *please specify
What types of NRT are you aware of?	Have you used any of these treatments? ☐ Yes* ☐ No *please specify
Please list the health risks associated with smoking and diabetes.	If still smoking, have you made any positive changes regarding your smoking?

Goals	
What are your goals for 6/12-mth follow-up?	What can I do to help you achieve these goals?

APPENDIX E

Instructions for Completion of

The Perceived Control of Diabetes Scales

The following questions are about the causes of situations which might happen to you. We ask you to imagine that the events described have happened to you recently.

While events may have many causes, we want you to pick one only – the ***major*** cause of the situation as you see it. Please write this cause in the space provided after each event.

Next, we want you to answer some questions about the cause by circling the most appropriate number on a sliding scale from 6 to 0.

Health Psychology Research, Dept of Psychology, Royal Holloway, University of London, Egham, Surrey, TW20 0EX, UK

Imagine that you have recently become unacceptably overweight.

Write down, in the space below, the single most likely cause of becoming overweight.

Now rate this cause on the following scales:

1. To what extent was the cause due to something about you?

Totally due to me	**6**	**5**	**4**	**3**	**2**	**1**	**0**	Not at all due to me

2. To what extent was the cause due to the treatment recommended by your doctor?

Totally due to treatment recommended	6	5	4	3	2	1	0	Not at all due to treatment **recommended**

3. To what extent was the cause something to do with other people or circumstances?

Totally due to other people or circumstances	6	5	4	3	2	1	0	Not at all due to other people or circumstances

4. To what extent was the cause due to chance?

Totally due to chance	**6**	**5**	**4**	**3**	**2**	**1**	**0**	Not at all due to chance

5. To what extent was the cause controllable by you?

Totally controllable by me	6	5	4	3	2	1	0	Totally uncontrollable by me

6. To what extent was the cause controllable by your doctor?

Totally controllable by my doctor	6	5	4	3	2	1	0	Totally uncontrollable by my doctor

7.To what extent do you think you could have foreseen the cause of becoming overweight?

Totally foreseeable by me	6	5	4	3	2	1	0	Totally unforeseeable by me

Imagine that for several days you have found high levels of sugar when you tested your blood or urine.

Write down, in the space below, the single most likely cause of high sugar levels.

_____

_____

Now rate this cause on the following scales:

1. To what extent was the cause due to something about you?

Totally due to me	**6**	**5**	**4**	**3**	**2**	**1**	**0**	Not at all due to me

2. To what extent was the cause due to the treatment recommended by your doctor?

Totally due to treatment recommended	6	5	4	3	2	1	0	Not at all due to treatment **recommended**

3. To what extent was the cause something to do with other people or circumstances?

Totally due to other people or circumstances	6	5	4	3	2	1	0	Not at all due to other people or circumstances

4. To what extent was the cause due to chance?

Totally due to chance	**6**	**5**	**4**	**3**	**2**	**1**	**0**	Not at all due to chance

5. To what extent was the cause controllable by you?

Totally controllable by me	6	5	4	3	2	1	0	Totally uncontrollable by me

6. To what extent was the cause controllable by your doctor?

Totally controllable by my doctor	6	5	4	3	2	1	0	Totally uncontrollable by my doctor

7.To what extent do you think you could have foreseen the cause of high levels of sugar?

Totally foreseeable by me	6	5	4	3	2	1	0	Totally unforeseeable by me

Imagine that you have been able to keep your weight at an acceptable level for a period of several weeks and you have felt fit and well.

Write down, in the space below, the single most likely cause of this period of good weight control and sense of general well being.

Now rate this cause on the following scales:

1. To what extent was the cause due to something about you?

Totally due to me	**6**	**5**	**4**	**3**	**2**	**1**	**0**	Not at all due to me

2. To what extent was the cause due to the treatment recommended by your doctor?

Totally due to treatment recommended	6	5	4	3	2	1	0	Not at all due to treatment **recommended**

3. To what extent was the cause something to do with other people or circumstances?

Totally due to other people or circumstances	6	5	4	3	2	1	0	Not at all due to other people or circumstances

4. To what extent was the cause due to chance?

Totally due to chance	**6**	**5**	**4**	**3**	**2**	**1**	**0**	Not at all due to chance

5. To what extent was the cause controllable by you?

Totally controllable by me	6	5	4	3	2	1	0	Totally uncontrollable by me

6. To what extent was the cause controllable by your doctor?

Totally controllable by my doctor	6	5	4	3	2	1	0	Totally uncontrollable by my doctor

7.To what extent do you think you could have foreseen the cause of feeling fit and well?

Totally foreseeable by me	6	5	4	3	2	1	0	Totally unforeseeable by me

Imagine that you have successfully avoided the complications of diabetes such as problems with your feet.

Write down, in the space below, the single most likely cause of the successful avoidance of diabetic complications such as problems with your feet.

Now rate this cause on the following scales:

1. To what extent was the cause due to something about you?

Totally due to me	**6**	**5**	**4**	**3**	**2**	**1**	**0**	Not at all due to me

2. To what extent was the cause due to the treatment recommended by your doctor?

Totally due to treatment recommended	6	5	4	3	2	1	0	Not at all due to treatment **recommended**

3. To what extent was the cause something to do with other people or circumstances?

Totally due to other people or circumstances	6	5	4	3	2	1	0	Not at all due to other people or circumstances

4. To what extent was the cause due to chance?

Totally due to chance	**6**	**5**	**4**	**3**	**2**	**1**	**0**	Not at all due to chance

5. To what extent was the cause controllable by you?

Totally controllable by me	6	5	4	3	2	1	0	Totally uncontrollable by me

6. To what extent was the cause controllable by your doctor?

Totally controllable by my doctor	6	5	4	3	2	1	0	Totally uncontrollable by my doctor

7.To what extent do you think you could have foreseen the cause of problems with your feet?

Totally foreseeable by me	6	5	4	3	2	1	0	Totally unforeseeable by me

Imagine that you have reduced your weight to a satisfactory level after a period when you gained too much weight.

Write down, in the space below, the single most likely cause of this weight reduction.

Now rate this cause on the following scales:

1. To what extent was the cause due to something about you?

Totally due to me	6	5	4	3	2	1	0	Not at all due to me

2. To what extent was the cause due to the treatment recommended by your doctor?

Totally due to treatment recommended	6	5	4	3	2	1	0	Not at all due to treatment recommended

3. To what extent was the cause something to do with other people or circumstances?

Totally due to other people or circumstances	6	5	4	3	2	1	0	Not at all due to other people or circumstances

4. To what extent was the cause due to chance?

Totally due to chance	6	5	4	3	2	1	0	Not at all due to chance

5. To what extent was the cause controllable by you?

Totally controllable by me	6	5	4	3	2	1	0	Totally uncontrollable by me

6. To what extent was the cause controllable by your doctor?

Totally controllable by my doctor	6	5	4	3	2	1	0	Totally uncontrollable by my doctor

7.To what extent do you think you could have foreseen the cause of gaining too much weight?

Totally foreseeable by me	6	5	4	3	2	1	0	Totally unforeseeable by me

Imagine that you have managed our diabetes successfully, living life as you wished while also keeping your glucose (sugar) levels under control

Write down, in the space below, the single most likely cause of managing your diabetes successfully.

Now rate this cause on the following scales:

1. To what extent was the cause due to something about you?

Totally due to me	6	5	4	3	2	1	0	Not at all due to me

2. To what extent was the cause due to the treatment recommended by your doctor?

Totally due to treatment recommended	6	5	4	3	2	1	0	Not at all due to treatment recommended

3. To what extent was the cause something to do with other people or circumstances?

Totally due to other people or circumstances	6	5	4	3	2	1	0	Not at all due to other people or circumstances

4. To what extent was the cause due to chance?

Totally due to chance	6	5	4	3	2	1	0	Not at all due to chance

5. To what extent was the cause controllable by you?

Totally controllable by me	6	5	4	3	2	1	0	Totally uncontrollable by me

6. To what extent was the cause controllable by your doctor?

Totally controllable by my doctor	6	5	4	3	2	1	0	Totally uncontrollable by my doctor

7.To what extent do you think you could have foreseen the cause of keeping your sugar under control?

Totally foreseeable by me	6	5	4	3	2	1	0	Totally unforeseeable by me

Appendix F

Smoking Locus of Control Scale

The following is a questionnaire that considers some of the reasons why people may or may not succeed in giving up smoking. (For the purpose of this scale, to 'succeed in stopping smoking' means having stopped for at least six months without starting again.)

Listed below are a number of statements about giving up smoking. We would like you to indicate the extent to which you agree or disagree with each statement, by placing a circle around the number on the scale which best represents your view. The scale ranges from 'Strongly Disagree' (0) to 'Strongly Agree' (5). Thus the more strongly you ***agree*** with a statement, then the ***higher*** will be the number you circle; and the more strongly you ***disagree*** with a statement, then the ***lower*** will be the number you circle.

Please make sure you consider every statement and that you circle only **one number** per statement.

As much as you can, try to respond to each statement independently and try not to be influenced by your previous choices. This is a measure of your personal views; there are no right or wrong answers. Just respond according to how you really feel.

It may be that at the moment you have no wish to stop smoking. If this is so, please fill out the scale anyway – imagining yourself at a time when you do wish to stop smoking.

Health Psychology Research, Dept of Psychology, Royal Holloway, University of London, Egham, Surrey, TW20 0EX, UK. Page 1of 2

	Strongly Disagree	Moderately Disagree	Slightly Disagree	Slightly Agree	Moderately Agree	Strongly Agree
1. For me, stopping depends on encouragement to give up from society as a whole	0	1	2	3	4	5
2. If I want to stop smoking, I've got to make it happen myself	0	1	2	3	4	5
3. If I fail to stop smoking, it's because the people closest to me didn't help me enough	0	1	2	3	4	5
4.If I succeed in stopping smoking, it will be because of my own determination	0	1	2	3	4	5
5. There is no such thing as a technique or treatment which can make it easy for me to stop smoking	0	1	2	3	4	5
6. I was destined *not* to stop smoking	0	1	2	3	4	5
7. For me, to stop smoking would depend on having the support of someone I care a lot about	0	1	2	3	4	5
8. I could stop smoking if I attended a good stop smoking clinic	0	1	2	3	4	5
9. There's nothing that my family or friends can do to help me stop smoking	0	1	2	3	4	5
10. If I fail to give up smoking, it's because I wasn't meant to be a non-smoker	0	1	2	3	4	5
11. There is nothing that health professionals (e.g. doctors, psychologists) can do to help me stop smoking	0	1	2	3	4	5

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Appendix G – Fagerstrom Small Test for Nicotine Dependence

Which therapy is right for you?

	Questions		**Answers**	**Points**
1.	How soon after you wake do you smoke your first cigarette		Within 5 minutes 6 – 30 minutes 30 – 60 minutes After 60 minutes	❑ 3 ❑ 2 ❑ 1 ❑ 0
2.	Do you find it difficult to refrain from smoking in places where it is forbidden (at work, on a plane, for example)		Yes No	❑ 2 ❑ 1
3	Which Cigarette would you most hate to give up?		First one in morning All others	❑ 2 ❑ 1
4.	How many cigarettes in a day do you smoke?		31 or more 21 – 30 11 – 20 10 or less	❑ 3 ❑ 2 ❑ 1 ❑ 0
5	Do you smoke more frequently during the first hours after waking than during the rest of the day?		Yes No	❑ 2 ❑ 1 ❑
6.	Do you smoke if you are so ill that you are in bed most of the day?		Yes No	❑ 2 ❑ 1

Points Total 1 – 3

You have a low dependence on nicotine and may benefit from using NRT occasionally to supplement your willpower. Use low strength 2 mg Gum or Microtab or if you think you are likely to miss the physical act of smoking, try an Inhalator.

Points Total 4 – 5

You have a medium dependence on nicotine. If you smoke at regular intervals throughout the day, try using a patch. Alternatively, if you have a less regular smoking pattern, low strength 2mg Gum or Microtab may be more appropriate. If you are likely to miss the hand-to-mouth action of smoking, try the inhalator.

Points Total 6 – 7

You have a high dependence on nicotine. If you smoke regularly throughout the day, you may find the Patch helpful. If you prefer to control how much nicotine you use and when you use it, try the full strength 4mg Gum or Microtab at the higher dose.

Points Total 8 - 10

You have a very high dependence on nicotine. You would benefit from using an NRT product with a high nicotine content that offers you flexibility such as the Nasal Spray, full strength 4mg Gum or Microtab at the higher dose.

APPENDIX H

INTERVENTION METHOD DURING CONSULTATION:

(to be used in conjunction with Diabetes and Smoking Cessation Education Programme)

PHASE I: Quick Assessment

Rapport – *"What sort of smoker are you?", "Tell me a bit about your smoking?", "You may well be fed up with people lecturing about your smoking. I won't do that but it would help me if I understood how you* ***really feel*** *about your smoking"*

Motivation/Confidence to quit – *On a scale of 1 – 10*

****

PHASE II: Patient identifies problems and solutions

Motivation/Confidence: Useful questions:

- *"Why are you at (chosen number) and not at 1?"*
- *"What would need to happen to get you from (chosen number) to (higher number)?"*

Useful strategies:

- Pros and cons: *"What you like/dislike about smoking?"*
- How can I help you get from (chosen number) to (higher number)?" Brainstorming
- *Help patient select* ***general*** *problem area first*
- *Encourage patient to say what* ***could*** *work*
- ***DO NOT*** *offer a solution*
- ***Patient chooses best option***
- Non-judgemental information regarding:

---

1. Health risks- **CHD, STROKE, HIGH BP**, **CIRCULATION, NERVE DAMAGE**
2. Services- **HOSPITAL, DROP-IN CLINICS, GP, PHARMACY**
3. NRT - **PATCHES, GUM, INHALATOR, MICROTAB, LOZENGES, NASAL SPRAY**
4. Other- **ZYBAN, CHAMPIX**

****

PHASE III: Goals and follow-up

Goals: Reinforce value in small gains and openness. Patient set manageable goal?

- May relate to number of cigarettes smoked
- May relate to factors that influence smoking
- If not ready to set any goals, keep communication open; *"Things do change…Can we agree to leave the door open on that one?"*

Follow-up:

- Find out how best they think I can help them attain their goals, i.e. follow-up, support, NRT

APPENDIX I - Diabetes and Smoking Leaflet (DSCEP)

DIABETES AND SMOKING: ARE YOU AT RISK?

Smoking is an independent risk factor for diabetes and can aggravate the risk of serious disease and premature death.

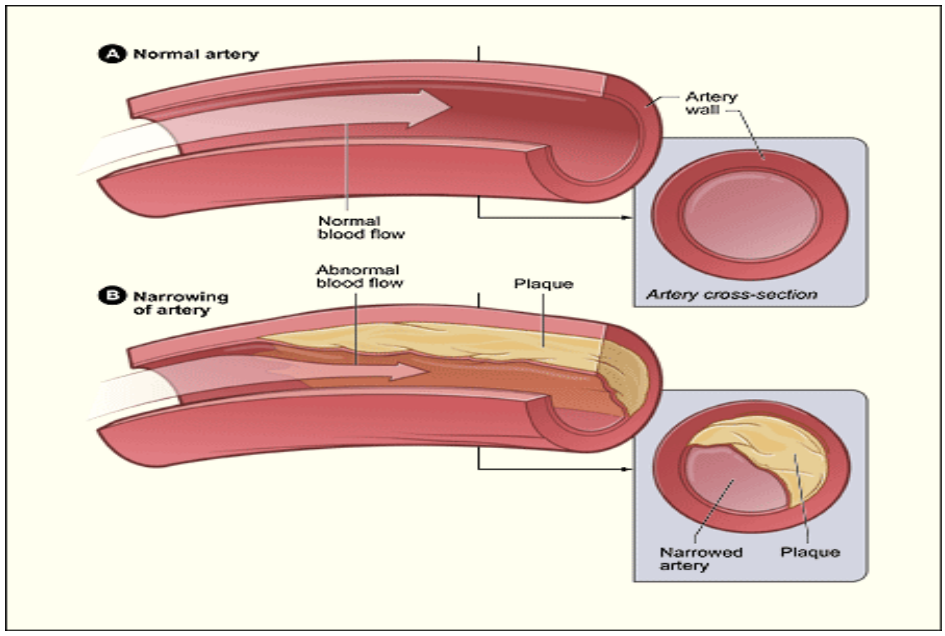
Smoking v's a healthy heart

People with diabetes are at greater risk of:

Atherosclerosis	**Angina**
Heart Attack	**Stroke**
High Blood Pressure	**Mini Stroke**
Nerve Damage	**Eye Damage**

What Is Atherosclerosis?

Atherosclerosis is the hardening and narrowing of the arteries. It is caused by the slow buildup of plaque on the inside of walls of the arteries. Plaque is made up of fat, cholesterol, calcium, and other substances found in the blood. As it grows, the buildup of plaque narrows the inside of the artery and, in time, may restrict blood flow. When this happens, the organ supplied by the blocked artery starves for blood and oxygen. The organ's cells may either die or suffer severe damage.

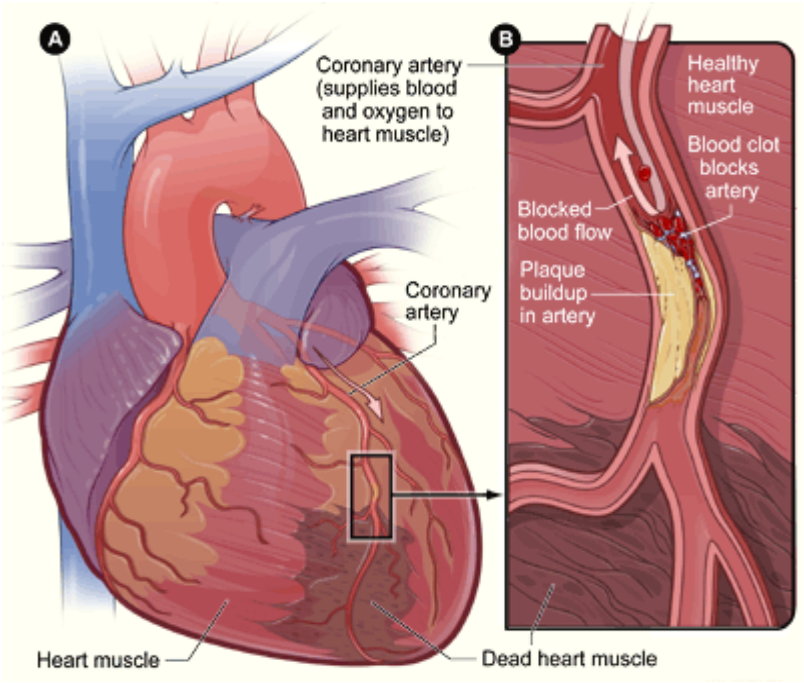


What Is Angina?

Angina is a symptom of heart disease that can cause chest pain or discomfort when your heart muscle does not get enough blood due to plaque build up.

What Is a Heart Attack?

A heart attack occurs when blood flow to a section of heart muscle becomes blocked due to plaque build up. If the flow of blood isn't restored quickly, the section of heart muscle becomes damaged from lack of oxygen and begins to die.

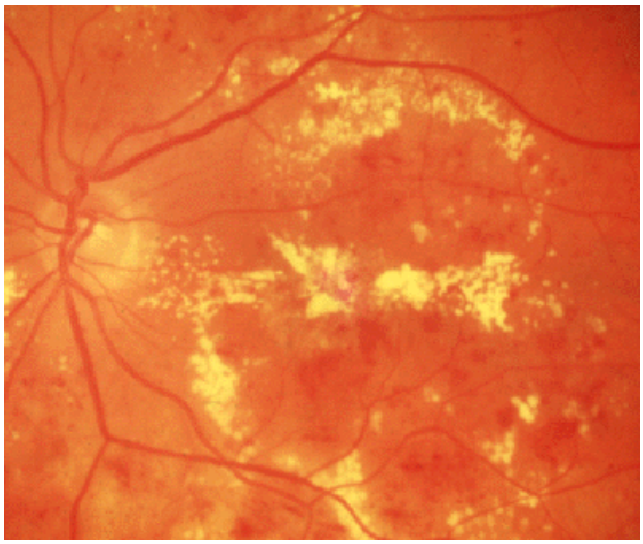


What is Stroke?

A stroke can occur when the blood supply to part of the brain is suddenly interrupted or when a blood vessel in the brain bursts, spilling blood into the spaces surrounding brain cells. Brain cells die when they no longer receive oxygen and nutrients from the blood or there is sudden bleeding into or around the brain.

What is Retinopathy?

Retinopathy is the name given to 'disease of the retina' due to diabetes. Blindness from retinopathy can be prevented by having regular eye checks and controlling sugar levels. Smoking **triples** the retinopathy progression rate of diabetic complications.

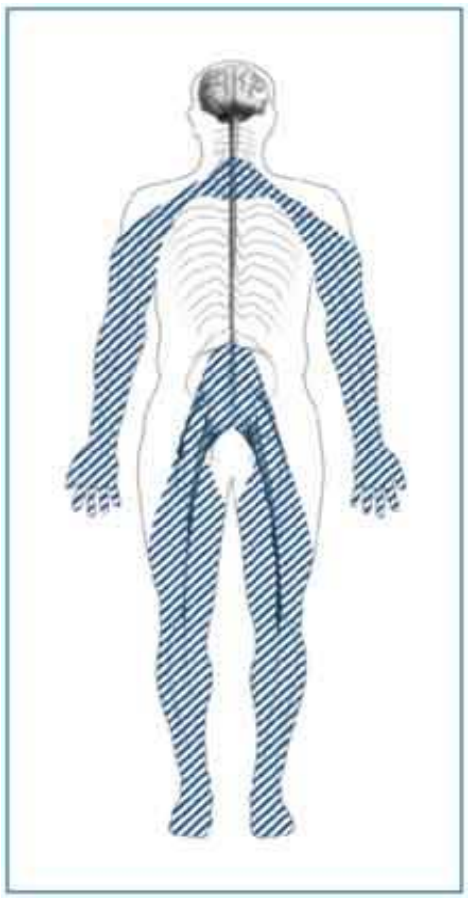


What is Nerve Damage (Neuropathy)?

Diabetes can cause damage to nerves throughout the body. Neuropathies lead to numbness and sometimes pain and weakness in the hands, arms, feet, and legs. Problems may also occur in the digestive tract, heart, and sex organs. Nerve damage can be caused by lifestyle factors such as smoking.

Peripheral Neuropathy

This type of neuropathy damages nerves in the arms and legs, hands and feet. Symptoms of peripheral neuropathy may include



- numbness or insensitivity to pain or temperature
- a tingling, burning, or prickling sensation
- sharp pains or cramps
- extreme sensitivity to touch, even a light touch
- loss of balance and coordination

Smoking significantly increases the risk of foot problems and amputation.

YOU CAN REDUCE YOUR RISK OF DEVELOPING

THESE COMPLICATIONS BY

STOPPING SMOKING TODAY

PLEASE CONTACT:

Margaret-Anne MacMillan
Smoking Cessation Advisor
Suite B, Falkirk Royal Infirmary
Friday mornings 9 am - 12 noon

Or

Smoking Cessation Specialist Nurse
Hut 5, Falkirk Royal Infirmary
Tel: 01324 678575

APPENDIX J

factsheet no:23

Smoking and diabetes

Action on Smoking and Health – November 2002

What is diabetes?
Diabetes occurs when the glucose level in the blood is too high because the body cannot use it properly. Glucose is a sugar that the body makes mainly from the carbohydrates in food. Glucose comes from the digestion of starchy foods such as bread, potatoes, chapatis, from sugar and other sweet foods and from the liver which makes glucose Glucose levels are controlled by the hormone insulin which is made and stored in the pancreas. Insulin helps glucose to enter the cells where it is used as fuel by the body and consequently the amount of glucose left in the bloodstream goes down.

Types of Diabetes
There are two types of diabetes: People with Type 1 diabetes (insulin-dependent) do not produce any insulin. People with Type 2 (non-insulin dependent) diabetes do not produce enough insulin, or the insulin that the body does produce doesn't work properly.

Type 1 diabetes is the less common form. This type usually develops in children and young adults but can occur at any age. It is thought that Type 1 diabetes occurs when the body's immune system destroys the cells that produce insulin but it's not known what causes this to happen.

About 90% of people with diabetes have Type 2 diabetes. This condition tends to develop gradually after the age of 40. However, increasingly, Type 2 diabetes is being diagnosed in younger people, including children. It appears that this is largely due to the fact that individuals have less active lifestyles and an increasing number are overweight. Both genetic and environmental factors contribute to the development of diabetes but the development of Type 2 diabetes is more likely if some or all of the following factors are also present: physical inactivity; being overweight; family history of Type 2 diabetes; previous diabetes in pregnancy. The condition is also more common in people of Asian and African-Caribbean origin. [1]

Prevalence of diabetes
In the UK, there are about 1.4 million people diagnosed with diabetes and a further 1 million are believed to be undiagnosed. It is estimated that there will be up to 3 million people with diabetes by 2010. There are about 33,000 deaths in the UK attributable to diabetes – about 1 in 7 of all deaths. At least half of these deaths are from cardiovascular disease. [2]

Health consequences
People with diabetes are at greater risk of raised blood pressure, heart disease, stroke, kidney disease, nerve damage and eye complications such as retinothapy

(disorders of the retina). [3]

Links between smoking and diabetes

There is a growing body of evidence to suggest that smoking is an independent risk factor for diabetes and that among people with diabetes, smoking aggravates the risk of serious disease and premature death.

In the US Nurses' Health Study, 114,247 women were followed for 8 years and 2,333 cases of type 2 diabetes were confirmed. After controlling for multiple risk factors, the relative risk of diabetes was 1.42 among women who smoked 25 or more cigarettes a day compared with non-smokers, suggesting a moderate association between smoking and the subsequent development of diabetes. [4]

A similar study of 41,810 middle aged men found that those who smoked more than 25 cigarettes daily had a relative risk of diabetes of 1.94 compared with non-smokers. [5]

A prospective study of Japanese men concluded that age of smoking initiation and number of cigarettes smoked were major risk factors for developing diabetes. [6] Similarly, data from the US Cancer Prevention Study 1 found that as smoking increased so the rate of diabetes increased for both men and women. [7]

People with diabetes already have an increased risk of heart disease, which is further elevated if they smoke. Diabetes acts in several ways to damage the heart: high glucose levels affect the walls of the arteries making them more likely to develop fatty deposits which in turn makes it more difficult for the blood to circulate. People with diabetes are more likely to have high blood pressure and high levels of fats such as triglycerides. They are also more likely to have lower levels of the protective HDL cholesterol. **1**

Insulin Resistance

Smoking has also been identified as a risk factor for insulin resistance which can lead to diabetes. People with insulin resistance cannot properly use insulin and such people may initially have higher than normal amounts of insulin circulating in their blood, a condition known as hyperinsulinemia.

Several factors, including genetics and obesity, increase a person's risk of insulin resistance and smoking has also been shown to increase the risk of this condition. It is believed that catecholamines, a type of hormone, are produced in greater quantity in smokers and act as an antagonist to insulin action. **3** A study of 40 patients with Type 2 diabetes found insulin resistance was markedly aggravated among those who smoked. [8]

Smoking, diabetes and premature death

The elevated risk of heart disease among people with diabetes increases the risk of premature death. In one study of women aged 60 to 79 who smoked and developed Type 2 diabetes, an estimated 65 per cent of the cardiovascular disease deaths among the subjects was attributed to the interaction of cigarette smoking and diabetes. [9] The same study suggested that smoking may trigger fatal events in people with diabetes whose circulation has been compromised due to vascular disease, or blood vessels damaged by a combination of smoking and diabetes. A large prospective study of US nurses found that among those with diabetes the relative risks of mortality were 1.31 for past smokers, 1.43 for current smokers of 1-14 cigarettes per day, 1.64 for smokers of 15-34 cigarettes per day, and 2.19 for current smokers of 35 or more cigarettes per day. [10]

The effect of smoking on complications of diabetes

Smoking is associated with multiple complications of diabetes. Nephropathy (kidney disease) has been shown to be common in Type 1 diabetic patients who smoke [11] and smoking increases the risk of albuminuria in both types of diabetes. [12] [13] (Albuminuria refers to the presence of protein in the urine and can indicate signs of kidney disease.) Another small study of 33 people with type 2 diabetes with kidney disease found that smokers' kidney function declined more rapidly than that of non-smokers, despite drug treatment, suggesting that smoking cessation could slow the progression of kidney disease in people with diabetes who use ACE inhibitors. [14]

The relationship between cigarette smoking and retinothapy (disorders of the retina) is less well defined than that of other microvascular complications of diabetes.[15] However, some studies have found an association between smoking and diabetic retinopathy. [16] **11**

Smoking is also a documented risk factor for both the development and progression of various types of neuropathy (damage to the peripheral nervous system). A retrospective case control study of type 1 and type 2 diabetic patients found that current or ex-smokers were significantly more likely to have neuropathy than individuals who never smoked (64.8% vs. 42.8%).[17] A more recent prospective study found that cigarette smoking was associated with a 2-fold increase in risk.[18]

Benefits of smoking cessation

There is overwhelming evidence that stopping smoking reduces the risk of cardiovascular disease, lung disease, cancer and stroke. [19] (See also ASH Fact sheet 11: What happens when you give up smoking.) As diabetes increases the risk for heart disease and stroke, it follows that stopping smoking will reduce the

risk of complications from diabetes such as heart disease. Few studies have evaluated smoking cessation treatment specifically for people with diabetes but the limited research available suggests that smokers with diabetes may be less successful in quitting than smokers without diabetes and that intensive strategies should be considered to optimise successful cessation. **15**

One possible explanation for the lower quitting rates among people with diabetes is the fact that stopping smoking is associated with weight gain and this is likely to be of concern in people who have diabetes and are already overweight. One US study found that concerns about weight gain among smokers with Type 1 diabetes were particularly prevalent among women, obese smokers, and those in poor metabolic control. **[20]** Fear of weight gain was cited by 49% of smokers.

A recent British prospective study of 7,735 men aged 40-59 years found that cigarette smoking was associated with a significant increase in risk of diabetes, even after adjustment for age, body mass index, and other potential confounding factors. The benefit of giving up smoking was only apparent after 5 years of smoking cessation and risk reverted to that of never-smokers only after 20 years. Men who gave up smoking during the first 5 years of follow-up showed significant weight gain and subsequently higher risk of diabetes than continuing smokers. However, the authors concluded that in the long term, the benefits of giving up smoking outweigh the adverse effects of early weight gain. **[21]**

Stopping smoking also reduces the risk of premature death. The US Nurses' Study found that among women with Type 2 diabetes who had stopped smoking for 10 or more years had a mortality relative risk of 1.11 compared with diabetic women who were never smokers.**10**

In the light of the growing evidence demonstrating that smoking is an independent risk factor for diabetes and that it is also an aggravating factor for diabetes complications, smoking cessation advice should be a routine component of diabetic care. Concerns about weight gain should be addressed by health care providers whilst emphasising the fact that the health benefits of smoking cessation far outweigh post cessation weight gain, even in people who are focused on weight management.

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APPENDIX K

factsheet no:11

What happens when you stop smoking

Action on Smoking and Health – July 2001

The desire to stop smoking

Many smokers continue smoking not through free choice but because they are addicted to the nicotine in cigarettes. A report by the Royal College of Physicians found that nicotine complied with the established criteria for defining an addictive substance. The report states: "On present evidence, it is reasonable to conclude that nicotine delivered through tobacco smoke should be regarded as an addictive drug, and tobacco use as the means of nicotine self-administration." **[1]**

Surveys have consistently shown that at least 70% of adult smokers would like to stop smoking. **[2]** A 1999 survey found that, of those who expressed a desire to quit, a third were very keen to stop. **2** The same survey found that the more a person smokes the less faith that person has that he or she can stop. The most important element of the cessation process is the smoker's decision to quit, with the aid or method of secondary importance. However, those who use aids such as nicotine replacement therapy double their chances of successfully quitting. **[3]** Smokers wishing to quit may find it helpful to telephone the national helpline on 0800 169 0169. Pregnant women seeking help in stopping smoking should call 0800 169 9169 where specialist counsellors are available from 1pm to 9pm, 7 days a week, to give advice. QUIT also operates specialist advice lines in the main Asian languages and in Turkish and Kurdish.

BENEFICIAL HEALTH CHANGES WHEN YOU STOP SMOKING

Stop smoking and the body will begin to repair the damage done almost immediately, kick-starting a series of beneficial health changes that continue for years. **[4]**

Time since quitting

Beneficial health changes that take place

20 minutes

Blood pressure and pulse rate return to normal.

8 hours

Nicotine and carbon monoxide levels in blood reduce by half, oxygen levels return to normal.

24 hours

Carbon monoxide will be eliminated from the body.
Lungs start to clear out mucus and other smoking debris.

48 hours

There is no nicotine left in the body.
Ability to taste and smell is greatly improved.

72 hours

Breathing becomes easier.
Bronchial tubes begin to relax and energy levels increase.

2 - 12 weeks

Circulation improves.

3 - 9 months

Coughs, wheezing and breathing problems improve as lung function is increased by up to 10%.

1 year

Risk of a heart attack falls to about half that of a smoker.

10 years

Risk of lung cancer falls to half that of a smoker.

15 years

Risk of heart attack falls to the same as someone who has never smoked.

Withdrawal symptoms

Withdrawal symptoms are the physical and mental changes that occur following interruption or termination of drug use. They are normally temporary and are a product of the physical or psychological adaptation to long-term drug use, requiring a period of re-adjustment when the drug is no longer ingested. In the case of smoking, some of these are: **[5]**

Withdrawal symptom

Duration

Proportion of those trying to quit who are affected

Irritability / aggression - Less than 4 weeks - 50%

Depression - Less than 4 weeks - 60%

Restlessness - Less than 4 weeks - 60%

Poor concentration - Less than 2 weeks - 60%

Increased appetite - Greater than 10 weeks - 70%

Light-headedness - Less than 48 hours - 10%

Night-time awakenings - Less than 1 week - 25%

Craving - Greater than 2 weeks - 70%

Weight gain

The possibility of weight gain is often of particular concern to those who want to give up smoking. More than 80% of smokers will gain weight once they quit smoking, but the long-term weight gain is on average only 6-8lbs for each smoker who quits. **[6]** However, this is the weight gain made without recourse to any special attempts at dieting or exercise and it presents a minor health risk when compared to the risk of continued smoking. In addition, improved lung function and some of the other health benefits of giving up smoking are likely to make exercise both easier and more beneficial.

Pipes & cigars

Some smokers switch to pipes or cigars in the belief that this is a less dangerous form of smoking. However, such smokers may incur the same risks and may even increase them, especially if they inhale the pipe or cigar smoke. **[7]**

Smoking cessation aids

There are two proven pharmaceutical aids to stopping smoking: nicotine replacement therapy and bupropion, known by its tradename, Zyban.

Nicotine replacement therapies (NRT), such as chewing gum, skin patch, tablet, nasal spray or inhaler, are designed to help the smoker to break the habit while providing a reduced dose of nicotine to overcome withdrawal symptoms such as craving and mood changes. Studies have shown that NRT roughly doubles the chances of a smoker successfully quitting compared to someone using no therapy. **[8]**

Bupropion, (**Zyban)** works by de-sensitising the brain's nicotine receptors and has shown promising results in clinical trials. The course of treatment lasts around 8 weeks. It is only available on prescription under medical supervision. Zyban is safe for most healthy adults but there are side effects, the most serious of which is the risk of seizures (fits). This risk is estimated to be less than 1 in 1000 but other less serious side effects such as insomnia, dry mouth and headaches are more common. An independent review by the Consumers' Association concluded that "when used in a specialist setting and in conjunction with regular counselling, bupropion is at least twice as effective as placebo in helping patients to stop smoking". **[9]**

Other cessation aids

Acupuncture and hypnosis. A review of alternative methods of aids to stopping smoking found little evidence to support the effectiveness of either acupuncture or hypnosis as a means of stopping smoking, but such methods may suit some

smokers. **[10]**

Herbal cigarettes. These are not recommended as an aid to giving up smoking because they produce both tar and carbon monoxide. Some brands have a tar content equivalent to tobacco cigarettes. In addition, the use of herbal cigarettes reinforces the habit of smoking, which smokers need to overcome.

Clinics and self-help groups. Smokers who are motivated to quit the habit may benefit from cessation clinics or self-help groups, although smokers should be cautious about claims of high success rates made by some clinics. A review of smoking cessation products and services found that smokers are up to four times more likely to stop smoking by attending specialist smokers' clinics than by using willpower alone. **[11]** As part of the Government's review of the NHS, more smoking cessation clinics are being established by health authorities and primary care groups. **[12]**

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APPENDIX L

Nicotine Replacement Therapy (NRT), Zyban and Champix

ALWAYS CHECK THE SUITABILITY OF NRT, ZYBAN AND CHAMPIX WITH YOUR GP OR PHARMACIST, AS IT WILL BE USED WITH DIABETES MEDICINES.

Nicotine Replacement Therapy (NRT), Zyban and Champix are products that are used to help smokers quit. They are not cures but they do make it easier to stop.

Smokers using NRT, Zyban or Champix are twice as likely to quit as smokers who do not. NRT, Zyban and Champix are available on prescription from your GP and most types of NRT can also be bought over the counter from your local Pharmacy.

NRT, Zyban and Champix are most effective when used with support. e.g. The Diabetes and Smoking Cessation Education Programme. However you will still need lots of willpower and determination to quit smoking.

What is NRT?

NRT products contain nicotine but not the disease causing tar or carbon monoxide found in tobacco smoke. Different types of NRT are available:

- ***Skin Patches*** – Look like sticking plasters and are stuck onto the skin. The nicotine is absorbed through the skin.
- ***Chewing Gum*** – Chewed carefully and rested between teeth and gum. Nicotine is absorbed through the mouth lining.
- ***Inhalator*** – Looks like a plastic cigarette and is inhaled like a cigarette. Nicotine is absorbed through the mouth and throat lining.
- ***Microtab*** – Tiny nicotine pills which are allowed to dissolve in the mouth. Nicotine is absorbed through the mouth lining.
- ***Lozenge*** – Large nicotine pills which dissolve in the mouth. Nicotine is absorbed through the mouth lining.

- ***Nasal Spray*** – A nicotine mist is sprayed into the nose and is absorbed through the nasal lining. (This is available by prescription only and is not commonly used).

How Does NRT Work?
NRT gives you a lower dose of nicotine than tobacco smoke but without the harmful effects of tar and carbon monoxide. It provides your body with a safe, regular dose that prevents or reduces the urge to smoke.

You will not get the same 'hit' as you get from a cigarette, because the nicotine takes longer to be absorbed than from inhaled tobacco smoke.

Most NRT products are designed to be reduced over time, to wean you off nicotine.

When Do I Start NRT?
You should start NRT on your quit day. For the first week use the full dose.

All types of NRT (except the patches which are left on all day) should be taken every hour, about 15 times a day. You can top up in between if you feel you need more, as it is important to use enough NRT to prevent you smoking.

Is NRT Safe?
NRT is very safe. It does not cause cancer and has no long-term adverse effects.

Will I Get Addicted To NRT?
NRT will not cause addiction, as you are already addicted to nicotine. While using NRT you will switch your addiction from cigarettes to the NRT itself. This is safe and you will gradually reduce your use of NRT over time to wean yourself off it.

What Happens If I Smoke When Using NRT?
Smoking with NRT is not dangerous, as you won't overdose on nicotine. However, to be successful the programme asks participants not to smoke at all when using NRT.

If you are smoking occasionally it may be that you need a higher dose of NRT to reduce withdrawal symptoms. (e.g. Heavy smokers may need to use a high strength patch and a supply of gum, Microtabs or lozenges to get through the bad times).

If you are smoking regularly then this quit attempt will be unsuccessful. Stop taking the NRT and leave it at least six months before you make another quit attempt. This break is important as it enables you to recover before making a second attempt.

Can NRT have side effects?
Side effects can occur:

Patches cause reddening of the skin where they've been worn. They may also cause sleep disturbances. (Removing your patch before you go to bed can reduce this).

Chewing Gum can cause throat irritation and indigestion.

Inhalators, Microtabs and Lozenges can all irritate the throat and mouth.

Nasal Sprays can irritate the nose and throat.

It takes a few days to get used to using any NRT product. However most side effects are minor and will improve over time.

How Long Should I Use NRT For?
NRT should be used for 2 – 3 months, but you can continue to use it for as long as you feel you need it. However, you will only get a prescription for the first three months, after that you will have to pay the full amount for your treatment. After they've quit, many people find that it helps to keep some nicotine gum, Microtabs or lozenges in their pocket or handbag for 'emergencies'.

Are There Long Term Risks With NRT?
NRT is very safe and can be continued for long periods of time if necessary.

Who Can Use NRT?
Almost all smokers can use NRT, but only the Microtab is licensed for use in pregnancy. Smokers who smoke less than 10 cigarettes a day may find that the gum, Microtabs or lozenges suit them best as they can be taken when needed after the first week of quitting. (During the first week it is recommended that the full dose be taken. This means using the gum, lozenge or Microtab every hour, about 15 times a day).

What Types Of NRT Are Available?

Product	Dosage	Pros	Cons
16-hour PATCH **Designed for wearing during the day.** **Best used for 8 -12 weeks** **(Use for at least 4).**	Amount of nicotine in each patch varies for each manufacturer but there are usually 2 or 3 different sizes. Start with the largest patch and change to smaller patches over a 2-3 month period.	Easy to use – put on in the morning and remove at night. Very discreet. No one need know. Good for heavy smokers who can 'top up' using gum, Microtabs or lozenges.	Might find you have early morning cravings. No oral satisfaction. Possible skin reaction. Takes 4-8 hours to reach a steady level. Can be used in any workplace.
24-hour PATCH Wear constantly during the day and night. Remove old patch and apply new one every morning. Used for 8 -12 weeks (Use for at least 4).	Amount of nicotine in each patch varies for each manufacturer but there are usually 2 or 3 different sizes. Start with the largest patch and change to smaller patches over a 2-3 month period.	Easy to use – Remove old patch and replace with a new one every morning. Helps to avoid cravings first thing in Morning. Good for heavy smokers who can 'top up' using gum, Microtabs or lozenges.	Some users experience sleep disturbances (vivid dreams or nightmares). No oral satisfaction. Possible skin reaction. Takes 4-8 hours to reach a steady level. Can be used in any workplace.

GUM Use for at least 4 weeks then whenever you feel you need it.	**2mg or 4mg.** Use at least 15 pieces a day for the first week. Then gradually cut down. Ensure you are using the correct chewing technique.	Use as and when required. Fairly discreet. Easy to carry with you for emergencies and difficult times both during and after quitting. Good for light to moderate smokers (or used in conjunction with patches for heavy smokers).	Some people don't like the taste, as it is a medicine not a sweet. Others don't like using gum as it takes a long time to chew. Nicotine absorbed through mouth lining therefore you should not swallow or it is wasted. Unsuitable for use in workplaces where eating is not allowed on duty. (E.g. Working with chemicals, food manufacturing, call centres, etc)
SPRAY Use for 8 weeks then reduce dose for 2 weeks.	Can be used once or twice and hour for first week (no more than 40 doses in 24 hours) then gradually cut down.	Fast relief for heavy smokers with easy control of dose.	Can feel self-conscious using it in public. Can cause irritation to the nose. More likely to lead to dependence. Only available on prescription - some GP's unlikely to prescribe. May be difficult to use in public workplaces (E.g. shops). Unsuitable for use in workplaces where eating is not allowed because of risk of contamination (E.g. working with chemicals or food manufacturing, etc).
INHALATOR Use for 8 weeks then reduce dose for 2 weeks.	6-12 cartridges for first eight weeks then 3-6 for two weeks, reducing to 0 over the next two weeks.	Keeps your hands and mouth occupied and easy to control dose.	Can feel self-conscious using it in public. Not recommended for heavy smokers. Can maintain the habit of putting cigarette substitute in the mouth. Unsuitable for use in workplaces where eating is not allowed on duty. (E.g. Working with chemicals or food manufacturing, etc).
MICROTAB/ LOZENGE Use for 12 weeks then gradually reduce dose.	8-24 per day depending on whether a heavy or light smoker. (Use at least 15 pieces a day for the first week).	Very discreet and easy to control dose. Side effects minimal. Microtab is the only NRT licensed for use with pregnant women.	Some people don't like the taste, as it is a medicine not a sweet. Must not swallow or nicotine is wasted. Unsuitable for use in workplaces where eating is not allowed on duty. (E.g. Working with chemicals or food manufacturing, etc).

Zyban (Bupropion)

What Is Zyban?

Zyban is a drug that has been shown to reduce the urge to smoke and has been licensed to help people to quit smoking.

How Does It Work?

Zyban was originally developed as an antidepressant. In low doses it was found to be effective in helping people to quit smoking. Zyban reduces the desire to smoke and some withdrawal symptoms associated with stopping smoking. It is believed that it does this by acting on pathways in the brain that play a key role in nicotine addiction.

When Do I Start Using Zyban?

You start taking Zyban at least a week before you plan to stop smoking as it **takes** a while to have an effect.

Is Zyban Safe?

Zyban is available on prescription from your GP and is safe and effective when used correctly. However, there are some side effects: Approximately 1% of users will experience mild side effects such as insomnia, headaches or dry mouth. Zyban can also cause a slight sense of disorientation, so beware of this if driving or operating machinery. These mild effects usually reduce over time. Rare but serious side effects can also happen, including seizure (fits), rashes and severe allergic reactions. If these occur then you must stop using Zyban immediately. Zyban may also react with other medicines including some that can be bought over the counter from Pharmacies. Therefore always tell your Pharmacist that you are using Zyban before buying any medicines.

How Long Should I Use Zyban For?

In total a 9 Week course of Zyban is given. For the first 6 days, one 150 mg tablet is taken per day. From day 7 this is increased to two 150mg tablets per day, taken 8 hours apart. As the drug starts to take effect the desire to smoke is reduced. Patients can quit smoking anytime from day 7 to day 14.

Your GP will give you a prescription for the first 2 – 4 weeks and will check that you are not experiencing problems with it before prescribing any more.

Is Zyban More Effective Than NRT?

Current research indicates that Zyban and NRT are equally effective at helping smokers quit.

Who Can Use Zyban?

Many people can safely use Zyban but it is not suitable for all people. **It is not recommended for:** Pregnant or breast-feeding women. Young people aged under 18. Patients with a history of epilepsy or seizures (fits). Patients with a history of head injury. Patients with a history of tumour of the brain or spinal column. Heavy drinkers or patients undergoing alcohol withdrawal. Patients withdrawing from benzodiazepines (a type of tranquillizer). Patients with eating disorders. Patients with cirrhosis of the liver. Patients with bipolar disease (manic depression). Patients taking monoamine oxidise inhibitors (MAOI's - a type of antidepressant). Patients with diabetes. Elderly people or those with impaired liver of kidney function can use Zyban, but in a reduced dose. (Only one 150 mg tablet is taken per day throughout the course of treatment). The use of certain other drugs or the presence of other medical conditions may also mean that Zyban cannot be taken. Your GP will advise.

Champix (Varenicline)

What is Champix?

Champix is the trade name of a drug called varenicline. It is a non-nicotine based medicine designed to help people stop smoking. It is available as a tablet, usually taken once a day at a lower dose for the first few days building up to a stronger dose taken twice a day after a week. People start taking it one to two weeks before they plan to stop smoking, and it is usually taken for about three months.

What does it do?

Champix can help reduce the cravings and withdrawal symptoms associated with stopping smoking. Also if someone taking Champix smokes a cigarette they may find it less satisfying and less pleasurable than before, which can reduce the risk of a complete relapse.

Does it work?

Published research shows that Champix does increase a smoker's chance of stopping smoking. The results from these studies are very encouraging, but more research is needed. Based on the available evidence Champix has been licensed for use in the NHS in Scotland as a prescription option.

Where can I get it?

Champix is available on prescription in Scotland from your doctor.

Can anyone use it? Champix is not recommended for:

- Children under the age of 18
- Pregnant women or during breast-feeding
- Anyone who may be allergic to varenicline or any of the other ingredients
- Champix should be used with caution in people with kidney disease

It's important that you tell your doctor what other medicines you are taking (including those bought without a prescription) before Champix is prescribed for you, and to tell your doctor or pharmacist that you are taking Champix before you take any new medicines.

Are there side effects?

Some people may experience nausea (feeling sick), difficulty sleeping, abnormal dreams or headaches. People who experience side effects should seek their doctor's advice, since this is a new drug it is especially important that you report any side effects.

How does Champix compare with Nicotine Replacement Therapy and Zyban?

Research shows that the best success rates for stopping smoking are achieved through specialist advice and support from trained professionals in combination with the use of stop smoking medications. Champix, NRT and Zyban have all been shown to work in helping people to stop smoking. In clinical trials Champix was found to be more effective than Zyban in helping patients to stop smoking. NRT can be bought over the counter and is also available on prescription, while Champix and Zyban are only available on prescription. Your doctor or pharmacist will be able to advise which is the most suitable product and form of delivery for you.

FINALLY…

Stopping smoking is the best thing that you can do for your health.

APPENDIX M - HOW TO STOP SMOKING AND STAY STOPPED –

(NHS BOOKLET SUBMITTED IN HARD COPY)

APPENDIX N - READY TO STOP SMOKING? WHERE TO FIND HELP NEAR YOU –

(NHS LEAFLET SUBMITTED IN HARD COPY)

APPENDIX O - PARTICIPANT DEBRIEF LETTER

Forth Valley NHS Board

Diabetes Care Centre

Falkirk District Royal Infirmary

Majors Loan

Falkirk

www.show.scot.nhs.uk/nhsfv

hpenquiries@fvhb.scot.nhs.uk

Date

Confidential

Our Ref Diabetes and Smoking Cessation Education Programme

Enquiries Margaret-Anne MacMillan

Extension 6094

Tel 01324 616041

Dear

Diabetes and Smoking Cessation Education Programme

I would like to thank you for participating in the Diabetes and Smoking Cessation Education Programme in Falkirk Royal Infirmary and for completing the somewhat lengthy questionnaires throughout the programme. Twenty-nine with Type 2 diabetes who smoked cigarettes took part. This letter is to inform you of the results.

The study was investigating whether participants believed their smoking and blood sugar control was under their own control (internality) or under the control of significant others, for example, doctor, nurse, (externality) and aimed to motivate participants to move toward taking control of their own health outcomes through the education programme, where appropriate. The study achieved this to some extent but not to significant levels. Previous research suggests that people demonstrating internality are more likely to take medicine and attend appointments.

The study found that participants' blood sugar levels had significantly reduced to nearer recommended levels, particularly among female participants. Carbon monoxide levels had also significantly reduced. The group were more motivated and more confident to stop smoking and disliked more about their smoking behaviour. Female participants were more concerned about smoking than the male participants were. Another significant result was in participant awareness of smoking cessation services and smoking cessation products that can help a quit attempt.

The information collected during the study will be used to write a thesis which satisfies one of the competencies of the professional doctorate in health psychology. You have my personal guarantee that all of the information will be used anonymously and that none of your personal information be disclosed.

Should you have any questions please contact me on 01324 616041 ext 6094.

Yours sincerely

Margaret-Anne MacMillan

Trainee Health Psychologist, Queen Margaret University

The effectiveness of smoking cessation interventions and lifestyle education programmes for patients with diabetes mellitus:

A Systematic Review.

Table of Contents **Page**

Abstract

Aim: To critically appraise the evidence for the effectiveness of behaviour change interventions that support good glycaemic control and smoking cessation.

Background: The World Health Organisation (WHO) has projected the prevalence of diabetes will double to an estimated 300 million people by 2025. Several studies suggest that smoking is associated with the development of diabetes and that insulin resistance is markedly aggravated among those who smoke. The major cause of morbidity and mortality associated with diabetes is from atherosclerotic macrovascular disease, which is intensified if the patient is a smoker. There is limited evidence for smoking cessation interventions aimed at patients with diabetes.

Methods: A systematic literature review was conducted using the following major inclusion criteria: systematic reviews and meta-analyses, randomized controlled trials with definitive and non-definitive results, cohort studies, case-controlled studies, cross-sectional surveys, case-reports, observational study, Type 2 diabetes, glycaemic control, smoking locus of control, perceived control of diabetes, motivational interviewing, adults over 25 years of age. Two reviewers independently assessed methodological quality using the Scottish Intercollegiate Guidelines Network (SIGN) critical appraisal checklist.

Results: The search strategy identified 4 smoking cessation intervention studies aimed at people with diabetes with a total of 940 participants, the majority being male. The timescale of the interventions ranged from 6 months to 4 years. The evidence ranged from 1+ to 1++ (SIGN, 2001). Statistically significant effects were found across all 4 studies suggesting that interventions are effective in raising awareness of the associated health risks and for initiating health behaviour change. The review found higher efficacy among interventions where those involved in delivery received training in smoking cessation and motivational interviewing techniques.

Conclusions: The review forms an evidence base for the efficacy of smoking cessation interventions aimed at people with diabetes. The results are presented in terms of recommendations for those developing interventions and directions for future research.

Introduction

As a result of an aging, increasingly obese and decreasingly physically active population, the global incidence and prevalence of diabetes mellitus is exploding (Eschwege *et al.*, 1997; King *et al.*, 1998; Boyle *et al.*, 2001). Type 2 diabetes mellitus represents 90% of all cases. The medical and public health challenges are further compounded by the observation that patients with diabetes have considerable risk for cardiovascular disease (CVD) with up to 80% of deaths attributable to CVD (Harris *et al.*, 1987).

The World Health Organisation (WHO) has projected that the prevalence of diabetes will double over the next 22 years to an estimated 300 million people by 2025 (King *et al.*, 1998). Sadly it is feared that these figures are grossly underestimated (Harris *et al.*, 1987; Saydah *et al.*, 2001; Taubert *et al.*, 2003).

Where the health of patients with diabetes who smoke cigarettes is concerned, the statistics are much worse. Several prospective cohort studies suggest that smoking is associated with the development of diabetes (Rimm *et al.*, 1993; Rimm *et al.*, 1995; Kawakami *et al.*, 1997). Further evidence suggests that insulin resistance is markedly aggravated among those who smoke. It is believed that catecholamines are produced in greater quantities in smokers and act as an antagonist to insulin action (Targher *et al.*, 1997).

The major cause of morbidity and mortality associated with diabetes is from atherosclerotic macro vascular disease, which is intensified if the patient is a

smoker. The combination of smoking and diabetes appear to heighten the development of macro vascular complications (UKPDS, 1991; Yudkin, 1993).

Changing these behaviours can reduce the risk of developing diabetes and delay the onset of long-term complications. Health locus of control has been shown to be related to whether an individual changes their health behaviour and moreover, to the communication style of the health professional. It is generally assumed that those who believe that they have control over their health will be more likely to perform a range of health promoting behaviours which in turn may reduce the patients risk of developing long-term complications (Rotter, 1966).

Patient ambivalence to behaviour change is a common problem faced by health care professionals (Rollnick, Heather and Bell, 1992). The main focus of motivational interviewing (MI) is facilitating behaviour change by helping patients to explore and resolve their ambivalence about their behaviour change (Rollnick and Miller, 1994) and consultations are more successful when there is a sharing of ideas (Tuckett *et al.*, 1985). MI appears consistent with a number of models of health behaviour including Locus of Control (Rotter, 1966). The greatest support for the efficacy of MI applied to health behaviour change is from smoking cessation studies (Stotts *et al.*, 2002; Valanis *et al.*, 2001; Eammonns *et al.,* 2001).

Previous research reports that Internal Health Locus of Control is the pivotal Health Locus of Control belief when predicting health behaviours (O'Hea *et*

al., 2005) and these findings are supported by Gillibrand and Stevenson (2006), in a study of patients with diabetes. ASH Scotland advises, 'In the light of the growing evidence demonstrating that smoking is an independent risk factor for diabetes and that it is also an aggravating factor for diabetes complications, smoking cessation advice should be a routine component of diabetic care'(ASH, 2002).

Few studies have evaluated the effectiveness of health behaviour change interventions for patients with diabetes who smoke, that help them quit smoking. However, there is evidence to suggest that a structured intervention managed by a single smoking cessation/behaviour change advisor is effective in changing the smoking behaviour of patients with diabetes (Canga *et al.*, 2000; Glasgow, 2000).

This review aims to evaluate the effectiveness of health behaviour change interventions specifically aimed at motivating patients with Type 2 diabetes to self-manage their condition more effectively and to stop smoking.

Method

As this study has a narrow, specific research question, the research design chosen is a systematic review of the literature (Cook and Mulrow *et al.*, 1997). Systematic reviews use explicit and reproducible methods in an attempt to reduce reviewer bias (Collins and Fauser, 2005). Systematic reviews do however have a number of limitations. The quality of the review findings are dependent on the quality of the literature being reviewed (Kunz and Oxman,

1998). The studies included in a systematic review should if possible be of high methodological quality and free from bias to allow any differences in outcome measures to be confidently attributed to the intervention being examined (Kunz and Oxman, 1998; Egger and Dickinson *et al*., 2001). The comprehensiveness of the literature search is also a crucial factor in the quality of a systematic review.

Intervention

Interventions of interest were ones where glycaemic control and smoking cessation were components of the intervention and also behaviour change interventions that were derived from perceived control of diabetes and smoking locus of control.

Participants

The review considered studies that included adults aged 25 years and over who had Type 2 diabetes and smoked cigarettes regularly.

Type of study

Randomised controlled trials, prospective studies and controlled trials were included in this review. There is general consensus that well planned and properly executed randomised controlled trials provide strong evidence on the efficacy of health behaviour change interventions (Jadad, 1998; Watson *et al.*, 2002). However, with so few studies available regarding smoking cessation interventions for people with diabetes other methodologies were included, for example, non-randomized controlled trials such as prospective studies can

often represent the best available evidence and can give an estimate of the nature, direction and size effects on which future research could be based (Petticrew and Roberts, 2006)

Outcome measures

Smoking cessation and glycaemic control within recommended levels were the outcome measures of the studies included in this review.

Electronic databases

Before the main search was conducted a small pilot search was carried out to test the effectiveness of the proposed search terms. Trial and error methods and the advanced search and thesaurus were used to modify the search terminology. The final search terms used were: smoking cessation intervention, smoking cessation programme, Type 2 diabetes, randomized controlled trial. For a more comprehensive list and overview of the process, please see the search strategy (Appendix A, pg39) and flowchart of the review process (Appendix B, pg41)

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As different databases have different strengths and weaknesses and to increase coverage, more than one database was selected to carry out the final search. Searches were carried out electronically on PsychInfo, Cochrane Library, Cinahl, PubMed, Medline, Science Direct, British Medical Journal, Lancet, Science Direct, Diabetes UK and ASH. Each of these databases were searched from 1989- 2009.

Searching by hand

Hand searches were made of the reference lists of the articles suitable for inclusion.

Data extraction

Information about the individual study characteristics included in the review was recorded on standardised checklist forms by two independent reviewers, (Appendix C).

Critical appraisal

Quality was assessed independently by two reviewers. The Scottish Intercollegiate Guidelines Network (SIGN 50) critical appraisal checklists and accompanying notes were used in this review to critically appraise the identified studies (SIGN, 2001). The SIGN critical appraisal tool was chosen because it provides a checklist for assessing the methodological quality of randomised controlled trials and gives an overall indication of the level of evidence provided through the use of a grading system which takes into consideration the complexity of the relationship between study type and quality. The methodological quality of the studies included judgements on: the randomisation process; allocation concealment; blinding; and the percentage of participants followed up, Table 1. Discussion between the two reviewers was used to resolve any differences in grades. In addition, a third reviewer was available in case disagreements could not be resolved.

Table 1: Methodology checklist and coding system (SIGN, 2001)

Checklist:

1. The study addresses an appropriate and clearly focused question.
2. The assignment of subjects to treatment groups is randomised
3. An adequate concealment method is used
4. Blinding
5. The treatment and control groups are similar at the start of the trial.
6. The only difference between groups is the treatment under investigation.
7. All relevant outcomes are measured in a standard, valid and reliable way.
8. What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?
9. Intention to treat analysis
10. Results are comparable for all sites (where the study is carried out at more than one site).

Coding system:

1++ All or most of the criteria have been fulfilled

1+ Some of the criteria have been fulfilled

1- Few or not criteria fulfilled

Results

A total of 7 potentially relevant articles were identified and screened for retrieval. These were then assessed to see whether they met the inclusion criteria or not. A total of 3 articles were then excluded for a number of reasons including: methodology reasons; benefits of smoking cessation to diabetes were not an outcome measure; study focussed more on smoking with little mention of diabetes. This process of attrition left 4 articles. The 4 articles included in this review are detailed in Table 2.

Table 2: Characteristics of included studies

Author/ date/ country	Population	Intervention	Number in each group	Outcomes and follow-up period	Key findings
Fowler *et al* ., (1989), Australia	N=34 participants with diabetes who smoke cigarettes daily Mean age = 50	Smoking cessation programme using visual display of coloured photographs	N=18 newly diagnosed (ndd) N=16 pre-existing (ped)	1. effects of timing of intervention 2. effects of content of intervention **Follow-up:** Outcome1 and 2. baseline then 1m, 3m and 6 month	Ndd participation significantly higher 2mths after diagnosis ($p< 0.10$) Ndd drop-out rate significantly higher in participants invited immediately after diagnosis ($p < 0.02$)
Gaede *et a.l*, (2001), Denmark	N=160 participants with type 2 diabetes who had previously taken part in Steno Type 2 study Mean age = 55 M = 120 F = 40	Lifestyle education programme focusing on diet, exercise and smoking	N=80 in behaviour change group N=80 in control group	Lower HbA1c Increased exercise Smoking cessation Follow-up: 4 years	Decrease in total fat intake larger than control group (41.2-34.2 vs. 41.9-38.3, $p = 0.0001$) Decrease in saturated fat compared with increase in control group (47-44 vs. 45-46, $p = 0.001$) Increase in polyunsaturated fats compared with controls (14-18 vs. 16-14, $p<0.0001$) No significant effects for smoking cessation although 43% had still stopped at 2-year follow-up
Canga *et al*., (2000), Spain	N= 280 Patients with Type 1 & 2 diabetes who smoked or stopped <1 year ago Mean age = 55 M = 240	40-minute nurse-led visit that included counselling, education and stop date	N= 133 control N= 147 intervention	1.difference in proportion of participants who stopped smoking between the control and intervention groups	N=31 (17%) stopped smoking 33% relapse significant reduction in mean no. of cigarettes smoked per day ($p<0.001$)

	F= 40			2. Mean no. of cigarettes smoked and stage of change Follow-up: 6 months	
Persson & Hjalmarson, (2005), Sweden	N= 368 Patients with diabetes mellitus who smoked cigarettes every day. aged 30 – 75 M = 210 F = 158	Eight group sessions in 2mths 45-60 minutes, discussing motivation, breaking habit, relapse prevention, pharmacotherapies. Individual follow-up calls, 3, 6 and 12 month follow-up. Smokers in the intervention group that did not want to be part of the group sessions received telephone calls at 6 and 12 months and were asked about their smoking habit.	N= 233 control group N= 145 intervention group	Smoking cessation Follow-up: 6 & 12 mths	N=42 participants self-reported stopping smoking ($p<0.01$): N=19 with group support N=23 with telephone support ($p<0.01$)

Participants

A total of 940 participants aged between 30 years and 75 years of age were included in the studies, with 640 of them being male. The studies were global and originated in Australia (Fowler *et al.*, 1989), Denmark (Gaede *et al.*, 2001), Spain (Canga *et al.*, 2000) and Sweden (Persson and Hjalmarson, 2005). All of the participants had a clinical diagnosis of diabetes mellitus and smoked cigarettes regularly.

Interventions

The length of the intervention periods ranged from 6 months to 4 years. There was considerable variation in the type of intervention and in the amount of information the authors provided. For example, in one study the participants

were not only randomized into control and intervention groups but also randomized into newly diagnosed with diabetes groups and pre-existing diabetes groups. These groups were then randomized further into one of two treatment groups where the study not only investigated the effects of the content of the anti-smoking programme but also the effects of the timing of the invitation to join the programme. The intervention lasted 6 months and involved face-to-face patient education using a portable visual display unit of coloured photographs. There is no description of what these photographs were or how and when they were used. Nonetheless, smoking cessation was validated by plasma cotinine levels (Fowler *et al.*, 1989).

In another study participants were randomized into a control group or an intervention group lasting 4 years. There was no further randomization which made this study much easier to follow. However, smoking cessation was measured by self-report and no biomedical markers such as cotinine levels or carbon monoxide levels were measured (Gaede *et al*., 2001).

There was also considerable variation in the training and expertise of the health professionals delivering the interventions. For example, Fowler *et al.,* (1989) do not mention the level of training required to deliver the Smokescreen programme whereas participants in the lifestyle education programme (Gaede *et al.*, 2001) were invited to take part in a standardized smoking cessation programme delivered by specialists who were already trained in smoking cessation techniques.

Canga *et al.,* (2000) and Persson and Hjalmarson, (2005) differ to the previous studies. They factored smoking cessation training into their protocol although to varying degrees. Canga *et al.,* (2000) report that the nurse delivering the intervention in their study spent two months studying the scientific literature on counselling on smoking cessation and had three weeks of practical training of her counselling skills by giving advice on smoking cessation to colleagues. Persson and Hjalmarson (2005) report that the nurse in their study received one half-day of training on motivational interviewing and smoking cessation.

Methodological characteristics

An overview of the methodological quality assessments of the studies is presented in Table 3. All of the studies had appropriate and clearly focussed questions and within each population the groups were similar at baseline. In these studies as with many public health studies, blinding of the participants and of those delivering interventions can be difficult. However, blinding of the outcome assessors should still have been possible. In only one study blinding was rated as 'well covered', (Canga *et al.*, 2001), in two studies it was rated as 'not applicable' (Gaede *et al.*, 2001; Persson and Hjalmarson, 2005) and in the final study blinding was 'not addressed', (Fowler *et al.*, 1989).

With regard to drop-out rates and participants lost to follow-up the numbers varied greatly. They are particularly high in the anti-smoking programme with 14/16 lost to follow-up according to the timing of joining the programme and 29/34 lost to follow-up according to the content of the anti-smoking

counselling (Fowler et al., 1989). In contrast the remaining three studies experienced very low attrition. The lifestyle education programme lost 11/149 participants (Gaede, *et al* ., 2001), the intervention study lost 2/280 participants (Canga *et al.,* 2000) and the intervention study in primary healthcare lost 21/368 participants (Persson and Hjalmarson, 2005). It should be noted that in some cases participants withdrew voluntarily or were lost to follow-up and in some instances they passed away.

Overall two studies were rated '1++' and two studies were rated '1+'.

Table 3: Overview of methodological quality

Author (date)	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Level of evidence**
Fowler *et al* ., (1989)	**WC**	**WC**	**AA**	**NAD**	**WC**	**WC**	**AA**	**WC**	**WC**	**NA**	**1+**
Gaede *et al*, (2001)	**WC**	**WC**	**AA**	**NA**	**WC**	**WC**	**WC**	**WC**	**WC**	**NA**	**1++**
Canga *et al*., (2000)	**WC**	**WC**	**WC**	**WC**	**WC**	**WC**	**WC**	**WC**	**WC**	**WC**	**1++**
Persson & Hjalmarson, (2005)	**WC**	**NA**	**NA**	**NA**	**WC**	**WC**	**WC**	**WC**	**WC**	**WC**	**1+**
WC = Well covered, AA – Adequately addressed, PA – Poorly addressed, NAD – Not addressed (i.e. not mentioned, or indicates that this aspect of study design was ignored), NR – Not reported (i.e. mentioned but insufficient detail to allow assessment to be made). NA – Not applicable											

*****Numbers 1-10 correspond with the 10 items listed in the methodology checklist (SIGN, 2001)

Outcomes

All four studies report statistically significant effects, more so those where intervention groups were compared to control groups. Fowler *et al.*, (1989), found that the timing of the invitation to join the anti-smoking programme for patients with diabetes had a significant effect. Agreement to participate was higher in the group invited two months after the diagnosis of diabetes with attrition significantly higher in the group approached to join without delay

following diagnosis ($p<0.02$). According to the self-reported data, cigarette consumption fell after the first session of the anti-smoking programme but could not be validated by the plasma cotinine measurements. Nor was the reduction statistically significant.

The results of the lifestyle education programme conducted in Denmark report a statistically significant effect of diet intervention but not for exercise and smoking cessation (Gaede *et al*, 2001). The decrease in total fat intake was significantly higher in the intervention group than it was in the control group. The intake of saturated fats decreased significantly in the intervention group as did the increase of polyunsaturated fatty acids intake. Six participants from the intervention group stopped smoking and had remained stopped by the end of the study as did five participants from the control group. Although welcome outcomes in themselves, these findings were not reported, as changes in smoking habits were not found to differ between groups.

The well conducted intervention study for smoking cessation in patients with diabetes (Canga *et al*, 2000), found that at 6-month follow-up, the incidence of smoking cessation was 17% in the intervention group compared with 2.3% in the control group. This was a 14.7% difference (95% CI 8.2 – 21.3%). A significant reduction was found in cigarette consumption at 6-month follow-up among participants who had continued to smoke. The mean number of cigarettes smoked per day in the intervention group decreased from 20 at baseline to 15.5 compared to 19.7 to 18.1 in the control group ($p < 0.01$).

The study by Persson and Hjalmarson (2005), also found statistically significant differences between the intervention group and the control group. At 12-month follow-up 20% of participants in the intervention centres and 7% of participants in the control centres had stopped smoking ($p < 0.01$). Smokers who participated in group treatment reported 40% smoking cessation whereas smokers in the intervention group who did not take part in the group treatment reported 14% smoking cessation. This result is significantly lower than for group treatment ($p < 0.01$).

Although the studies found statistically significant outcomes for smoking cessation, Fowler *et al.,* (1989), did not find the anti-smoking programme to be cost effective. They found the intervention to be extremely time-consuming and suggest that such an intervention may be beyond the financial resources available to most specialist diabetes departments. The study recommends that patients with diabetes be encouraged to attend a community-based specialist smoking cessation programme.

This is the format that Gaede *et al's.,* (2001), lifestyle education intervention followed which may account for the impressive 43% smoking cessation success rate at 2-year follow-up.

Although the intervention study conducted by Canga *et al* (2000), does not mention cost effectiveness *per se*, they acknowledge that their protocol was also very time-consuming. This may indicate that the intervention was not cost effective to implement.

Discussion

The aim of this systematic review was to critically appraise the evidence of the effectiveness of smoking cessation interventions for patients with diabetes mellitus. Four studies were identified from the literature search, 1 prospective study, 2 randomized controlled trials and 1 controlled study and appraised for methodological quality. Smoking cessation and lifestyle interventions were found to be effective in motivating people with diabetes to stop smoking. However, the evidence suggests that the outcomes may be dependent on the timing of the intervention, who delivered the intervention and their level of training, location, the health professionals' commitment to the intervention in terms of both time and resources, and the commitment of the participants (Fowler *et al*, 1989; Gaede *et al*, 2001; Canga *et al*, 2000; Persson and Hjalmarson, 2005).

More importantly, what is evident from these articles is the lack of a patient-centred approach and a psychological focus. The lifestyle interventions and education programmes measure smoking cessation outcomes and report that stopping smoking may reduce the risk of developing the long-term complications associated with diabetes. Three of the present studies do not allude to psychological elements or measure psychosocial outcomes even although Gaede *et al*., (2001) advise that a psychologist was involved in planning the lifestyle education programme. Canga *et al.,* (2000), did use the Stages of Change model in their study to measure participant attitudes toward smoking cessation but apart from this there is no psychological component

such as motivation to stop smoking or confidence to maintain behaviour change.

Motivation and confidence are key concepts when using motivational interviewing techniques as are readiness to change behaviour and resolving ambivalence (Rollnick *et al.*, 1992). The nurse in the intervention study conducted across Sweden received one half-day training in motivational interviewing and smoking cessation, however, according to the results, none of these concepts were measured or reported (Persson and Hjarmarlson, 2005).

Psychology and Diabetes

In the past diabetes and psychology were not always thought of as being complementary. This perspective is changing and with the use of psychology, the experience of the individual self-managing diabetes can be greatly improved. The role of the psychologist is useful when the individual with diabetes is required to change their lifestyle and adopt health enhancing behaviours, sometimes almost overnight. These changes may include moving from a sedentary lifestyle to an active one with more exercise, swapping unhealthy food for healthy food and stopping smoking. It will certainly include blood glucose monitoring.

The procedures required to monitor blood sugar levels and control diabetes can be very complicated and time-consuming and for many people can be overwhelming. As the majority of diabetes treatment is self-managed outside

the medical setting serious problems can result if the person lacks motivation and confidence. Their condition can deteriorate and result in amputation of limbs or blindness (Bradley, 1994).

In addition to the behavioural demands of diabetes emotional and social problems can arise. Diabetes is often perceived as a burden by those affected. It can be hard to accept the disease and feeling overwhelmed can result in depression. Individuals can become anxious through fear of complications or hypoglycemia and can become frustrated with the demands of self-management.

Social problems can result from diabetes as well. Many individuals who do not have diabetes can find it difficult to understand the needs of someone with diabetes. The knowledge, beliefs and behaviours of people with diabetes and their health care professionals may all affect diabetes control. Psychological perspectives can therefore be valuable in enhancing self-management. Several important interventions have been developed and evaluated by multi-disciplinary teams that include psychologists (Norris *et al*., 2001; Ismail *et al*., 2004).

The DAFNE study highlighted the benefits of measuring psychological outcomes in its evaluation of the diabetes education and training programme developed by Mulhauser's team and found that psychological outcomes improved markedly with glycaemic control. When only metabolic outcomes such as blood sugar levels are measured, health care professionals and

funding bodies may value new treatments if only blood sugar control improves. There may be little or no emphasis placed on psychological improvements and these therapies may not be offered as they are not deemed important. (DAFNE Study Group, 2002).

Generic measures focus on health and illness rather than the impact of diabetes. For example, measures of perceived health cannot be expected to detect diabetes related quality of life impairments or the psychological angst often associated with the demands and restrictions of long-term self-management and the risk of developing long-term complications. (Bradley 1994).

In contrast, questionnaires measuring psychological outcomes take into account issues important and relevant to people with diabetes (Bradley, 1994; Bradley and Speight 2002; Polonsky 2000; Pouwer *et al*., 2000). Those designed to be completed by study participants and patients, that ask appropriate and relevant questions, can highlight reasons for poor glycaemic control and indicate preferences for treatment and for complementary therapies such as relaxation techniques. Where problems are identified in one or more biomedical or psychological outcome, measures of psychological processes such as diabetes-related knowledge, self-management skills and behaviour, locus of control and coping strategies can indicate what action might be appropriate (Bradley 1994).

Psychological perspectives are already evident in many innovative approaches to diabetes care in hospital and community settings, in policy documents such as the Nationals Service Framework for Diabetes (Department of Health, 2003) and in clinical trial reports, demonstrating how psychologists can work with health care professionals to improve the lives of people with diabetes. It is imperative that this trend continues and psychologists become an integral part of the diabetes care team. Health behaviour change interventions and lifestyle education programmes must be informed by psychology and more importantly, measure psychological outcomes, through developing effective and relevant research projects.

Psychology and Smoking

Cigarette smoking is a highly addictive behaviour that can and does work on many levels. People can be physically addicted to the nicotine in cigarettes and psychologically addicted to the behavioural routines and rituals associated with smoking with the latter generally thought to be the stronger of the two.

The reasons people start smoking and continue to smoke can be wide and varied with many starting smoking in childhood or early adulthood. Some anti-smoking organizations claim that adolescents engage in smoking behaviours due to peer pressure and cultural influences. However, one study found that direct pressure to smoke cigarettes did not significantly affect adolescent smoking and consequently participants reported low levels of both normative and direct pressure to smoke cigarettes (Urberg *et al.*, 1990).

A similar study showed that individuals play a more active role in starting to smoke than has previously been thought and that social processes other than peer pressure need to be taken into account (Michell and West, 1996). Another study revealed that peer pressure was significantly associated with smoking behavior across all age and gender cohorts, but that intrapersonal factors were significantly more important to the smoking behavior of 12–13 year-old girls than same-age boys (Barber *et al*., 1999).

Hans Eysenck developed a personality profile for the typical smoker. Extraversion was the trait found to be most associated with smoking, and smokers tend to be sociable, impulsive, risk taking, and excitement seeking individuals (Eysenck *et al*., 1960). Although, personality and social factors may make people more inclined to smoke, the behaviour is a function of operant conditioning. During the early stages, smoking provides pleasurable sensations because of its action on the dopamine system and thus serves as a source of positive reinforcement (Skinner, 1938).

Because they are engaging in behaviour that has negative health effects, people who smoke tend to rationalize their behaviour and can develop convincing reasons why smoking is acceptable. For example, a smoker could justify the behaviour by concluding that everyone has to die eventually and therefore cigarettes do not actually make any difference. Additionally they could believe that smoking relieves stress or has other benefits that justify its risks. The reasons people give for this behaviour are broadly categorized as

addictive smoking, pleasure from smoking, tension reduction/relaxation, social smoking, stimulation, habit/automatism, and handling. Females are more inclined to report tension reduction/ relaxation, stimulation and social aspects as reasons for smoking (Berlin *et al*., 2003).

Some people who smoke often argue that the depressant effect of smoking allows them to calm their nerves and relieve stress, allowing for increased concentration. However, Imperial College London advises that, "*Nicotine seems to provide both a stimulant and a depressant effect, and it is likely that the effect it has at any time is determined by the mood of the user, the environment and the circumstances of use. Studies have suggested that low doses have a depressant effect, while higher doses have stimulant effect.* " (Montgomery *et al*., 2003).

A number of studies have shown that cigarette sales and smoking follow distinct time-related patterns. For example, in America cigarette sales have been shown to follow a strongly seasonal pattern, with increased sales in the summer months and decreased sales in the winter months (Chandra and Chaloupka, 2003). Similarly, smoking has been shown to follow distinct circadian patterns during the waking day with the high points usually occurring just after waking in the morning and just before going to sleep at night (Chandra et al., 2007).

It is clear from the evidence that smoking cigarettes is a complex behaviour that may require more than nicotine replacement therapy to aid cessation.

Brief psychological therapies for smoking cessation based on cognitive behavioural therapy, such as QUIT FOR LIFE (Marks, 1993) have shown to be effective with high efficacy and cost effectiveness compared to nicotine replacement therapies (Marks, Murray, Evans and Willig, (2002). Health care systems need to continue to build their capacity and infra-structure to increase public access to psychological therapies.

The final solution to tobacco control will require a multi-level approach consisting of economic, political, social and psychological interventions based on empirical evidence from research that measures, among other things, psychological outcomes.

Strengths and limitations of the review

A strength of this review is that a pre-defined system, i.e. the SIGN methodology checklist and level of evidence rating, was identified and used to critically appraise the quality of the included research (Scottish Intercollegiate Guidelines Network, 2001). Another strength of the review is that two reviewers were independently involved in the critical appraisal process.

A limitation of this review is that only English language papers were selected for inclusion due to resource constraints. This may be an issue because the prevalence of diabetes and smoking is high among the Asian population and it may be expected that a number of papers investigating smoking cessation interventions for people with diabetes have been published in the appropriate languages. Therefore, this review may suffer from language bias (Egger *et al.,* 2001). However, when searching the reference lists of the studies included,

no Asian publications that had smoking cessation rates for people with diabetes as an outcome measure, were identified.

Implications for practice

From the evidence presented in this review it is suggested that smoking cessation should be promoted among individuals with diabetes. There are many smoking cessation services operating across the UK at present but there is very little evidence for services specifically aimed at people with diabetes. One pilot programme has been running in Scotland, the Diabetes and Smoking Cessation Education Programme, and preliminary results are encouraging. It is important that health professionals are made aware of the health risks associated with smoking with diabetes and how behaviour change interventions can reduce the risk of developing long-term complications. It may be appropriate for health professionals to promote smoking cessation both in primary and secondary care and to offer support in both settings.

Implications for research

In the studies identified in this review the majority of participants were male. It is unclear whether the lower rate of female participants was due to the fact they were unavailable or if there is a lower incidence of smoking with diabetes among the target populations.

None of the studies identified for inclusion were set in the United Kingdom. There is a need for rigorous and robust randomized controlled trials in the UK that examine the impact of smoking cessation interventions and lifestyle

education programmes on people with diabetes. The studies should be designed in such a way that they aim to include more female participants and the studies should incorporate a psychological measure as it underpins behaviour and behaviour change.

Conclusions

Diabetes and smoking, singly, are a major public health issue and a leading cause of morbidity and mortality worldwide. The statistics for smoking with diabetes are even more of a concern and are projected to increase as the westernised world continues to gain weight and adopt a sedentary lifestyle. The burden placed upon the health service is also a concern and it too is expected to increase significantly. The evidence presented in this review suggests that smoking cessation interventions and lifestyle education programmes for adults with diabetes may be beneficial in reducing the prevalence of individuals smoking cigarettes which may, in turn, reduce the economic burden facing the NHS.

However, the literature in this review suggests that these programmes and interventions need to be designed in such a way that they engage the target audience and reduce attrition rates. Interventions should be designed to measure biochemical markers such as plasma cotinine and carbon monoxide levels and not rely on participants self-reports and should engage health behaviour change specialists instead of offering limited training to the health professionals responsible for delivering the intervention. More importantly the interventions need to include psychological measures as they will underpin

the intervention and affect the outcomes. Health professionals in a variety of healthcare settings have an important role to play in health promotion and need to be made aware of the evidence base for specialist smoking cessation programmes for patients with diabetes.

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Appendix A – Search Strategy

MAM – Margaret-Anne MacMillan NM – Neil McLean

Search	Keyword and phrases	No of hits	No of hits
PsychInfo		MAM	NM
1	Diabetes	10269	10269
2	Diabetes and smoking	587	587
3	Diabetes and perceived control	34	34
4	Type 2 diabetes and perceived control	6	6
5	Type 2 diabetes and perceived control and smoking	0	0
6	Type 2 diabetes or perceived control or smoking	26968	26968
7	Type 2 diabetes or perceived control and smoking	1410	1410
8	Type 2 diabetes and smoking	62	62
9	Type 2 diabetes and smoking and perceived control	0	0
10	Smoking cessation and type 2 diabetes	6	6
11	Smoking intervention and type 2 diabetes	1	1
12	Smoking intervention and type 2 diabetes and perceived control	0	0
13	Smoking cessation intervention and type 2 diabetes and perceived control	0	0
14	Smoking cessation intervention and type 2 diabetes	245898	245898
15	Type 2 diabetes and locus of control	13	13
16	Type II diabetes and locus of control	7	7
17	Type 2 diabetes and locus of control and smoking	0	0
18	Smoking and locus of control	196	196
19	Smoking and locus of control and type 2 diabetes	138	138
20	Smoking cessation and locus of control and type 2 diabetes	0	0
21	Intervention study and diabetes (and smoking)	7	7

Search	Keywords and phrases	No. of Hits	No. of Hits
CINAHL		MAM	NM
1	Diabetes	354,620	354,620
2	Diabetes and smoking	17,339	17,339
3	Diabetes and perceived control	29	29

4	Type 2 diabetes and perceived control	7	7
5	Type 2 diabetes and perceived control and smoking	0	0
6	Type 2 diabetes or perceived control or smoking	36,767	36,767
7	Type 2 diabetes or perceived control and smoking	8306	8306
8	Type 2 diabetes and smoking	373	373
9	Type 2 diabetes and smoking and perceived control	0	0
10	Smoking cessation and type 2 diabetes	42	42
11	Smoking intervention and type 2 diabetes	1	1
12	Smoking intervention and type 2 diabetes and perceived control	0	0
13	Smoking cessation intervention and type 2 diabetes and perceived control	0	0
14	Smoking cessation intervention and type 2 diabetes	1	1
15	Type 2 diabetes and locus of control	14	14
16	Type II diabetes and locus of control	1	1
17	Type 2 diabetes and locus of control and smoking	0	0
18	Smoking and locus of control	62	62
19	Smoking and locus of control and type 2 diabetes	0	0
20	Smoking cessation and locus of control and type 2 diabetes	0	0
21	Intervention study and diabetes (and smoking)	8	8

Search	Keywords and phrases	No. of Hits	No. of Hits
MEDLINE		MAM	NM
1	Diabetes	306319	306319
2	Diabetes and smoking	14791	14791
3	Diabetes and perceived control	23	23
4	Type 2 diabetes and perceived control	8	8
5	Type 2 diabetes and perceived control and smoking	0	0
6	Type 2 diabetes or perceived control or smoking	177,666	177,666
7	Type 2 diabetes or perceived control and smoking	38,824	38,824
8	Type 2 diabetes and smoking	1468	1468
9	Type 2 diabetes and smoking and perceived control	0	0
10	Smoking cessation and type 2 diabetes	119	119
11	Smoking intervention and type 2 diabetes	1	1
12	Smoking intervention and type 2 diabetes and perceived control	0	0

13	Smoking cessation intervention and type 2 diabetes and perceived control	0	0
14	Smoking cessation intervention and type 2 diabetes	2	2
15	Type 2 diabetes and locus of control	16	16
16	Type II diabetes and locus of control	0	0
17	Type 2 diabetes and locus of control and smoking	0	0
18	Smoking and locus of control	104	104
19	Smoking and locus of control and type 2 diabetes	0	0
20	Smoking cessation and locus of control and type 2 diabetes	0	0
21	Intervention study and diabetes (and smoking)	32	32

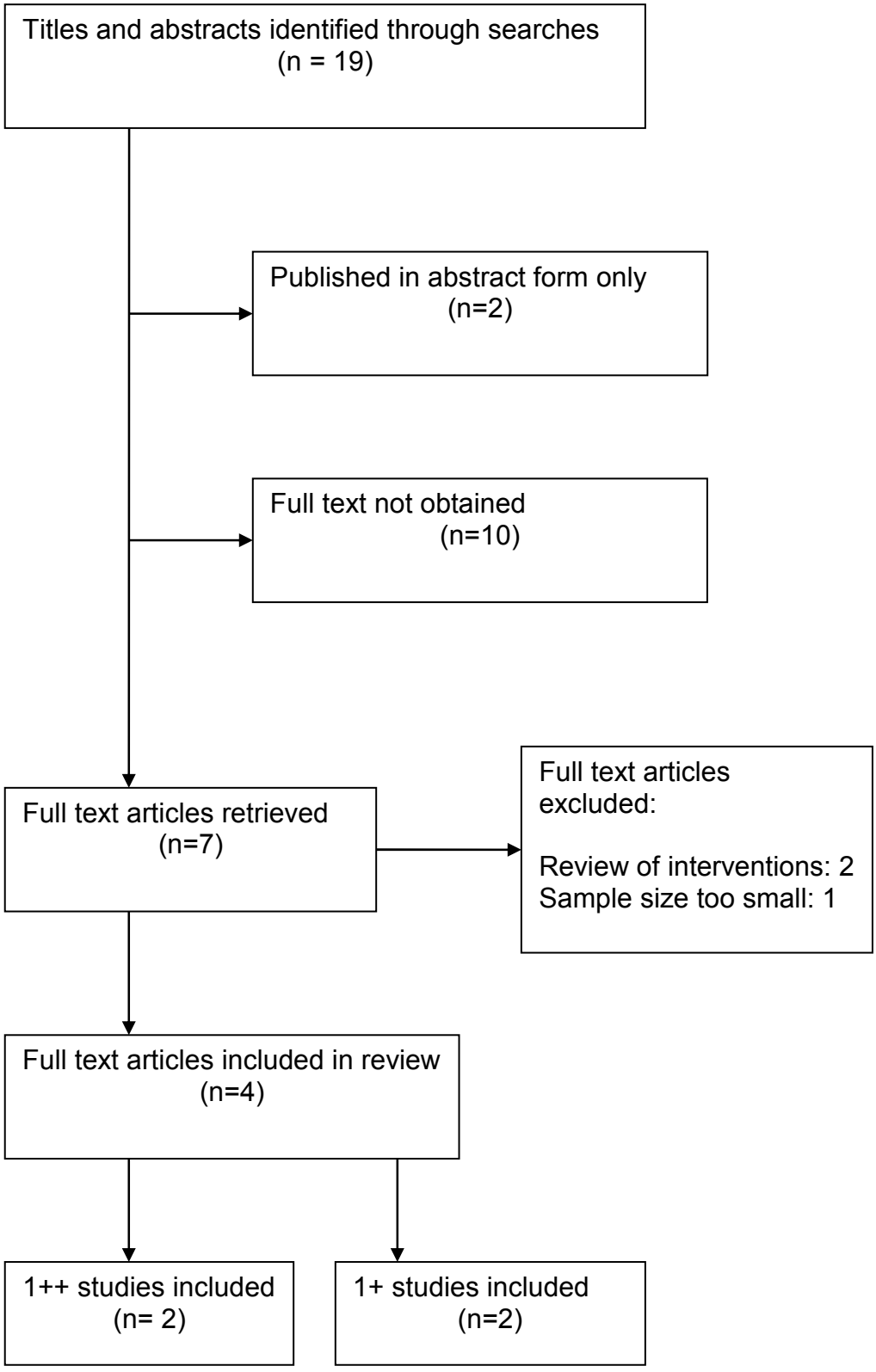
Search	Keywords and phrases	No of hits	No of hits
British Nursing Index		MAM	NM
1	Diabetes	10269	10269
2	Diabetes and smoking	587	587
3	Diabetes and perceived control	34	34
4	Type 2 diabetes and perceived control	6	6
5	Type 2 diabetes and perceived control and smoking	0	0
6	Type 2 diabetes or perceived control or smoking	26968	26968
7	Type 2 diabetes or perceived control and smoking	1410	1410
8	Type 2 diabetes and smoking	62	62
9	Type 2 diabetes and smoking and perceived control	0	0
10	Smoking cessation and type 2 diabetes	6	6
11	Smoking intervention and type 2 diabetes	1	1
12	Smoking intervention and type 2 diabetes and perceived control	0	0
13	Smoking cessation intervention and type 2 diabetes and perceived control	0	0
14	Smoking cessation intervention and type 2 diabetes	245898	245898
15	Type 2 diabetes and locus of control	13	13
16	Type II diabetes and locus of control	7	7
17	Type 2 diabetes and locus of control and smoking	0	0
18	Smoking and locus of control	196	196
19	Smoking and locus of control and type 2 diabetes	138	138
20	Smoking cessation and locus of control and type 2 diabetes	0	0

21	Intervention study and diabetes (and smoking)	1	1

Search	Keywords and phrases	No of hits	No of hits
Bmj.com		MAM	NM
1	Type 2 diabetes and smoking cessation and education programme	0	0
2	Type 2 diabetes and smoking cessation and intervention	0	0
3	Smoking and type 2 diabetes	0	0

Search	Keywords and phrases	No of hits	No of hits
Wileyinterscience.com			
1	Smoking and diabetes	2104	2104
2	Smoking cessation and diabetes	172	172
3	Effectiveness of 'and' smoking cessation intervention 'and' glycaemic control	0	0
4	Smoking 'and' diabetes 'and' provider advice	0	0
5	Tobacco control 'and' diabetes and effective intervention	0	0

Appendix B – Flowchart of Review Process



Grading system of studies in accordance with SIGN, (2001):

1++ = All or most of the criteria have been fulfilled
1+ = Some of the criteria have been fulfilled

Appendix C - Characteristics of Included Studies

Study identification	
Reviewer 1 **Reviewer 2**	Margaret-Anne MacMillan Neil McLean
Study number	1
Authors	Fowler, P.M., Hoskins, P.L., McGill, M., Dutton, S.P., Yue, D.K. and Turtle, J.R.
Article/report title	Anti-smoking Programme for Diabetic Patients: The Agony and the Ecstasy
Source (journal/year/vol/pages)	Diabetic Medicine, 1989. 6: 698-702
Aims of study	1.) To gather information by carrying out a survey of diabetic patients smoking habits and their knowledge of the health effects of smoking. 2.) To determine the optimal time and content of an anti-smoking intervention based on the outcome of the survey.
Methods	
Design of study	Knowledge Survey – individuals attending a diabetes outpatient clinic were randomly selected form the clinic waiting list by a diabetes specialist nurse and asked to complete a standardized questionnaire which investigated their past and present smoking habits. Interviewees were asked if they knew smoking was detrimental to their health and were asked to state how health could be affected by smoking. Ex-smokers were questioned as to the major reason for stopping smoking. Prospective Study – 1.) To investigate the effects of timing of invitation of join the anti-smoking programme – patients with newly diagnosed diabetes (ndd) were randomized to one of two treatment groups: (1) those approached to join the anti-smoking programme immediately upon presentation and (2) those approached to join the anti-smoking programme 2 months after initial presentation 2.) To investigate the effects of content of the anti-smoking programme – patients were randomized to one of two treatment groups: (1) counselling on general health risks of smoking according to the Smokescreen protocol and (2) counselling on the interaction between smoking and diabetic complications.

Follow up	1 month, 3 months and 6 months.		
Sampling (voluntary?)	Patients with newly diagnosed diabetes and patients with pre-existing diabetes identified as current cigarette smokers agreed to participate.		
Participants			
Inclusion criteria	Newly referred diabetic patients who were current cigarette smokers		
Gender	Knowledge Survey – 70 male, 62 female Prospective Study - details of numbers and group allocation not specified		
Number of eligible individuals **Number of included individuals**	n = 70 (n = 33 – ndd, n = 37 – ped) n = 18 ndd n = 16 ped		
	Total	Control	Intervention
Number randomised	18 ndd 16 ped	9 8	9 8
Age of individuals	ndd = 47 ± 9 yrs ped = 53 ± 13 yrs		
Intervention			
Setting	Royal Prince Albert Hospital, Diabetes c Centre, Sydney, Australia,		
Details of intervention	Smokescreen programme was designed for use by health professionals and involves face-to face patient education using a portable visual display unit of coloured photographs. Follow-up visits were used to reinforce knowledge and to encourage any successful quit attempts. 18 ndd and 8 ped participants were counselled according to Smokescreen. The remaining 8 ped participants received a modified programme characterized by specific information stressing the effects of smoking on diabetic complications.		
Duration of intervention	30 minutes		
Number of sessions	4		
Randomisation			
How was randomisation undertaken?	Not specified		
Details of randomisation	18 ndd participants were randomized equally to two treatment groups: (1) join anti-smoking		

	group immediately after presentation and (2) join anti-smoking group 2 months after presentation 16 ped participants were randomized equally to two treatment groups: (1) counselling about general health risks of smoking and (2) counselling about diabetes specific health risks of smoking

Outcome

What outcome variables used? Smokescreen anti-smoking programme		Variable	Measured by
	Primary	Effects of timing of invitation to join anti-smoking programme Effects of content of anti-smoking programme	Plasma cotinine level Self-reported smoking levels

Analysis

Type of analysis used	Chi Square			
Statistical techniques	Percentages, means ± standard deviation, effect size,			
Do techniques adjust for confounding?	No – there was a reduction in self-reported smoking levels which was not supported by the mean plasma cotinine levels. No further investigation of this was conducted			
Unit of analysis	Standardized questionnaire, Smokescreen anti-smoking programme			
Attrition gh – general health ds – diabetes specific		Timing of programme		Content of programme
	baseline	n=0 ndd n=0 ped		n=0 gh n=0 ds
	1 month follow-up	n=9 ndd n=5 ped		n= 1gh n=4 ds
	3-month follow-up	n=14 ndd n=12 ped		n=3 gh n=9 ds
	6-month follow-up	n=15 ndd n=14 ped		n=4 gh n=10 ds

Results

Outcome	Newly diagnosed group	Pre-existing diabetes group
Baseline: *Knowledge Survey – n=132:* 89% already aware that smoking is detrimental to health 10% - 23% aware that		

smoking can worsen diabetic complications. *Ex-smokers reasons for stopping – n=51:* Major reason was risk to general health		
Timing of invitation to join anti-smoking programme	Agreement to participate significantly higher in ndd participants 2 months after diagnosis ($p < 0.10$) Drop-out rate significantly higher in ndd participants invited immediately after diagnosis ($p < 0.02$)	
Content of anti-smoking programme	Results not reported by ndd or ped	High attrition rate in both counselling groups: gh = 4 lost to follow-up; ds = 10 lost to follow-up
Plasma continine levels and self-reported smoking levels	Results not reported by ndd or ped	No test of significance was conducted
Reduction in cotinine levels (1311-431) and cigarette consumption (22 – 5) for recruited participants (n=34) Reduction in cotinine levels (1147 – 431) and cigarette consumption (27 – 5) for participants completing the programme (n=6)	No significance testing occurred	

Authors conclusions

This study was difficult to follow with groups, subgroups and no clear definition of who was the intervention group and who was the control group, although further investigation suggests they may all have been intervention groups. Participants appeared to receive different interventions at different times therefore it is difficult to ascertain causality. For example, ndd participants were randomized to one of two intervention groups (1) those approached to join the anti-smoking programme immediately upon diagnosis and (2) those approached to join the programme 2 months after diagnosis. Formal anti-smoking information was omitted from the standard diabetes education programme for the latter group. It is therefore difficult to gauge whether the timing caused the effect or whether the anti-smoking programme caused the effect. It may have been more beneficial to have given both groups the same intervention while keeping the timelines the same.

Ped participants were randomized to one of two intervention groups (1) counselling on general health risks according to Smokescreen and (2) counselling on interaction between smoking and diabetes complications. All (n=18) ndd participants and 8 ped participants received Smokescreen while the remaining 8 ped participants received a modified programme emphasizing the interaction between smoking and diabetes complications. There is no indication

of what the modifications were and no mention of timing of intervention delivery, bearing in mind that all ndd participants had previously been subdivided by time.

It is difficult to draw conclusions based on the results presented. This may be due to the fact that this is a case control study and these have a high risk of confounding and a significant risk of relationships not being causal. It could also be due mainly to the inability to link interventions to outcomes because of generality of results and the lack of significance testing of results overall. Moreover, this study appeared to have a lot going on and focussed more on high attrition rates than the content of the education programme. Consequently the lack of effects may be due to study design or poor write up.

SIGN Grading : 1+

Study identification			
Reviewer 1 **Reviewer 2**	Margaret-Anne MacMillan Neil McLean		
Study number	2		
Authors	Gaede, P., Beck, M., Vedel, P., and Pedersen, O.		
Article/report title	Limited impact of lifestyle education in patients with Type 2 diabetes mellitus and microalbuminuria: results from a randomized intervention study		
Source (journal/year/vol/pages)	Diabetic Medicine, 2001, 18, 104-108		
Aims of study	To assess the effect of intensified education on lifestyle (diet, exercise and smoking) as part of an intensified multifactorial intervention over a 4-year period in patients with Type 2 diabetes mellitus and microalbuminuria		
Methods			
Design of study	Randomized intervention study Patients were randomly assigned to either an intensive group focussing on change of behaviour as well as polypharmacological treatment or to a control group receiving conventional treatment. Interviewers were not blinded to group allocation		
Follow up	Mean = 3.8 years		
Sampling (voluntary?)	160 participants who had previously been involved in the StenoType 2 Study were recruited.		
Participants			
Inclusion criteria	Patients with Type 2 diabetes who had previously participated in the Steno Type 2 Study		
Gender	M = 120 (75%), F = 40 (25%)		
Number of eligible individuals	160		
	Total	Control	Intervention

Number randomised	160	80	80
Age of individuals	Mean = 55.1 years		
Intervention			
Setting	Steno Diabetes Centre, Gentofte, Denmark		
Details of intervention	**Diet** – Individual consultations were delivered by clinical dietitian combined with group interventions delivered by the whole team – 6 consultations in first year. First 3 consultations were individual interviews discussing patient risk profile and goals for diet, exercise and smoking were set. Next 2 consultations were groups of 20, including spouses and discussed lifestyle attitudes, beliefs and habits. Educational approach was based on needs of patient and their spouse. 1st step - patients advised to trade high fat for low fat foods and simple for complex carbohydrates 2nd step – patients advised to reduce portion sizes 3rd step – introduce new foods and menu ideas 4th step – monitor effect of changes in diet **Exercise** – advice on exercise was given as part of the 6 educational sessions described above. Patients were advised to start exercising although no training sessions between patients and diabetes team were performed. **Smoking –** all patients in the intervention group who smoked, and their spouses, were invited to take part in a standardized smoking cessation programme 5 meetings in 8 weeks – group consultation for 14 people with follow-up at 3 and 6 month Patients advised on benefits of cessation, how to manage cravings, pharmacotherapy		
Duration of intervention	4 years		
Number of sessions	20 (baseline, 6 educational sessions in yr 1, 4 sessions in yr, 2, 3 & 4, 4-year follow-up)		
Randomisation			
How was randomisation	Not specified		

undertaken?	
Details of randomisation	Patients were randomized to an intensive multifactorial intervention comprising behaviour modification and polypharmacological therapy by a diabetes team consisting of a physician, a clinical dietitian and a nurse from Steno Diabetes Centre or randomized to a standard multifactorial intervention at their general practitioners.

Outcome

What outcome variables used?		Variable	Measured by
Diet – permanent qualitative and quantitative change in dietary fat with a high intake of polyunsaturated and monounsaturated fatty acids; low intake of saturated fatty acids; increase in intake of complex carbohydrate	Primary	Lower HbA1c Dietary fat intake Carbohydrate intake Weight	Blood sugar levels Fasting serum cholesterol levels
	Secondary	Exercise Smoking	Self- report although specific details not specified Self-report although specific details not specified

Analysis

Type of analysis used	Descriptive and inferential statistics Comparison of numerical variables between and within groups, comparison of categorical variables			
Statistical techniques	ANCOVA, Mann-Whitney, t-test, Wilcoxon, Chi-square			
Do techniques adjust for confounding?	No – during the study period from 1993 to 1997 there were several national campaigns focusing on healthy lifestyle which may have contributed to the significant reduction in fat intake in both groups. The advice to take more exercise did not take into account that some of the participants were amputees, had painful neuropathy, coronary disease and intermittent claudication and offered no suggestions on how these participants could exercise safely. The high success rate for smoking cessation may have been confounded by national campaigns and well-implemented advice at the community level The study design does not allow conclusions as to whether behaviour modification or drug therapy was the most effective in reducing diabetes complications Intervention comprised of individual interviews and group sessions with no indication of format participants preferred			
Unit of analysis	Evaluation interviews, procedure for measuring clinical and biochemical variables is not specified			
Attrition	Reasons	Total	Control	Intervention
	Voluntary withdrawal	5	2	3

	Died	6		
	Total	11		

Results

Outcome	Control	Intervention
Baseline	N = 76	N = 73
Post intervention Changes in exercise and smoking did not differ between groups		Decrease in total fat intake was larger than in control group (41.2-34.2 vs. 41.9-38.3, p = 0.0001) Decrease in saturated fat compared with increase in control group (47-44 vs. 45-46, p = 0.001) Increase in polyunsaturated fats compared with controls (14-18 vs. 16-14, p<0.0001) Increase in carbohydrate intake larger although not statistically significant.

Authors conclusions

A good and interesting study although the authors mention that a psychologist was involved in the planning process but no psychosocial outcome was included. This may have been missed opportunity and weakened the study as the success for permanent lifestyle change is dependent on the participants' degree of motivation, psychosocial condition and compliance. Apart from measuring fasting serum cholesterol, it is not evident what other measurements are in place other than self-reports. The study may have benefited from using carbon monoxide or cotinine testing equipment. Moreover, there was no measure of participants' levels of motivation and confidence particularly with regard to exercising. Developing an exercise class designed especially for the participants may have benefited many of them, particularly those who had experienced amputation.

SIGN Grading : 1++

Study identification			
Reviewer 1 **Reviewer 2**	Margaret-Anne MacMillan Neil McLean		
Study number	3		
Authors	Canga, N., De Irala, J., Vara, e., Duaso, M.J., Ferrer, A. and Martinez-Gonzalez, M.A.		
Article/report title	Intervention study for smoking cessation in diabetic patients		
Source (journal/year/vol/pages)	Diabetes Care, 2000, 23, 10, 1455-1460		
Aims of study	To evaluate the effectiveness of a nurse-managed smoking cessation intervention in diabetic patients		
Methods			
Design of study	Randomized controlled trial in clinical and primary care setting.		
Follow up	Day before cessation – telephone call 2 weeks – follow-up visit 3 weeks – a letter sent 2 months – second follow-up visit 6 months – final evaluation		
Sampling (voluntary?)	Yes – all patients with diabetes who were registered either in the two primary care centres or in the two hospitals during the intervention period		
Participants			
Inclusion criteria	Patients with Type 1 and Type 2 diabetes who were current smokers or who had stopped for less than one year		
Gender	Males = 240, Females = 40		
Number of eligible individuals **Number of included individuals**	482 280		
	Total	Control	Intervention
Number randomised	280	133	147
Age of individuals	Mean =	55.8 yrs	54.4 yrs
Intervention			

Setting	University Clinic of Navarre and the Hospital of Navarre, Pamplona, Navarre, Spain
Details of intervention	Intervention consisted of a 40-minute nurse-led visit that included counselling, education and a negotiated cessation date. The follow-up consisted of telephone calls, letters and visits.
Duration of intervention	6 months
Number of sessions	5

Randomisation

How was randomisation undertaken?	Randomization was by a computer-generated allocation method and the process was blinded.
Details of randomisation	The nurse opened a sealed envelope that determined which condition the eligible patient would be assigned to

Outcome

What outcome variables used?		Variable	Measured by
	Primary	The difference in the proportion of participants who stopped smoking between the control and intervention groups	Urine cotinine levels
	Secondary	Mean number of cigarettes smoked and stage of change	Transtheoretical Model

Analysis

Type of analysis used	Descriptive and inferential statistics			
Statistical techniques	Two-tailed Fishers exact tests, two-tailed paired t-tests,			
Do techniques adjust for confounding?	No – participants who wanted it were given nicotine replacement therapy			
Unit of analysis				
Attrition	*Reasons*	Total	Control	Intervention
	Failed to keep appointment	23		
	Died	1		
	Lost to follow-up	1		

Results		
Outcome	Control	Intervention
Achieved smoking cessation (cumulative incidence validated by cotinine)	N=7 (2.3%)	N=31 (17.0%)
Falsely reported smoking cessation	N=3	N=4
Proportion of participants in relapse stage (TTM)	10.5%	33%
Mean number of cigarettes smoked per day -baseline -6-month follow-up	19.7 18.1(p=0.01)	20.0 15.5 (p<0.001)
No significant differences in the proportion of quitters across the different health care centres		

Authors conclusions

A well thought out study that endeavoured to minimise bias. However, there is no mention of participant motivation or confidence to stop smoking. The amount of training the nurse received may have had a negative impact on the results and perhaps a more experienced smoking cessation advisor would have benefited the study. It is not clear how the nurse determined the stage, of the stages of change model that each participant found themselves in, which may also have led to high rates of relapse. Having said that, 17% cessation after only 6-months is a good result.

SIGN Grading : 1++

Study identification			
Reviewer 1 **Reviewer 2**	Margaret-Anne MacMillan Neil McLean		
Study number	4		
Authors	Persson, L.G. and Hjalmarson, A.		
Article/report title	Smoking cessation in patients with diabetes mellitus: Results from a controlled study of an intervention programme in primary healthcare in Sweden		
Source (journal/year/vol/pages)	Scandinavian Journal of Primary Health Care, 2006, 24, 75-80		
Aims of study	To evaluate an intervention programme on smoking cessation in patients with diabetes mellitus in primary healthcare		
Methods			
Design of study	Regional controlled intervention study		
Follow up	6 months and 12 months		
Sampling (voluntary?)	Yes – patients registered with the primary care centres taking part in the study		
Participants			
Inclusion criteria	Patients with diabetes mellitus aged 30 – 75 years of age who smoked cigarettes every day.		
Gender	Males = 210, Females = 158		
Number of eligible individuals **Number of included individuals**	412 368		
	Total	Control	Intervention
Number randomised	N/A		
Age of individuals	Mean =	60.6	59.4
Intervention			
Setting	Sweden – 17 primary healthcare centres		

Details of intervention	1 telephone interview and follow-up telephone calls at 6 and 12 months. The structured telephone interview consisted of questions about length and amount of smoking and chronic diseases were registered. The intervention programme consisted of eight group sessions in a 2-month period, lasting 45-60 minutes, led by nurses educated in smoking cessation. Issues discussed were motivation to stop smoking, advice on how to break the habit, how to prevent relapse, pharmacotherapies and their use. After the group treatment participants received individual follow-up telephone calls and 3, 6 and 12 month follow-up. Smokers in the intervention group that did not want to be part of the group sessions received telephone calls at 6 and 12 months and were asked about their smoking habit.
Duration of intervention	12 months
Number of sessions	8

Randomisation

How was randomisation undertaken?	N/A
Details of randomisation	N/A

Outcome

What outcome variables used?		Variable	Measured by
	Primary	Smoking cessation	Self-report

Analysis

Type of analysis used	Descriptive and inferential statistics			
Statistical techniques	Chi-square using Yates correction or Fishers exact test, t-test			
Do techniques adjust for confounding?	No – participants in the intervention group that did not want to be part of the group sessions received a modified version of the intervention. This suggests that they did not receive the same level of intervention. No biochemical markers were measured therefore all smoking cessation rates were by self-report.			
Unit of analysis	questionnaires			
Attrition C = 223 I = 145	*Reasons*	Total	Control	Intervention
	Failed to keep appointment			
	Died	14	5	9
	Lost to follow-up	4	2	2

Results		
Outcome	Control	Intervention
Smoking cessation	N=10 participants stopped smoking	N=42 participants self-reported stopping smoking ($p<0.01$): N=19 with group support N=23 with telephone support ($p<0.01$)

Authors conclusions

The authors advise that the intervention was delivered by a diabetes nurse who was given one half day of training in motivational interviewing and smoking cessation. Both these topics are vast and cannot possibly be covered in one afternoon therefore the integrity of the intervention and the rigour of the study may have been compromised because of this. No biochemical markers were measured which was a missed opportunity as self-reports may have been exaggerated or misleading, even although the authors conclude that deception rates tend to be low. Participants should have received the same intervention and should all have received telephone interventions or received group interventions, not one format for some and a different format for others. Also the intervention was conducted across 11 primary healthcare centres with the resident diabetes nurses delivering the intervention. This equates to at least 11 people delivering the intervention therefore it is difficult to say whether the participants in each centre received the exactly the same intervention. Participants were encouraged to use pharmacotherapy to aid smoking cessation therefore it is difficult to attribute the success rate to the intervention. No consideration was given to participants levels of confidence to stop smoking. Although participant motivation was discussed during the telephone interviews, the findings have not been reported or discussed. All things considered, the success rate was good.

SIGN Grading : 1+